CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) IN THE TREATMENT OF KATTU MANTHAM FOR (CONSTIPATION) IN CHILDREN

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of

DOCTOR OF MEDICINE *(Siddha)*

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2015 - 2018

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) IN THE TREATMENT OF KATTU MANTHAM (CONSTIPATION) IN CHILDREN''** is a bonafide and genuine research work carried out by me under the guidance of **Dr.K.Suresh M.D(S).,Ph.D, Lecturer,** Department of Kuzhandhai Maruthuvam, National Institute of Siddha, Chennai -47, and the dissertation has not formed on the basis for the award of any Degree, Diploma, Fellowship or other similar title previously.

Date: **Signature of the Candidate**

Place: Chennai-47 (Dr. M.Lavanya)

CERTIFICATE

This is to certify that this dissertation work entitled **"CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) IN THE TREATMENT OF KATTU MANTHAM (CONSTIPATION) IN CHILDREN**" has been carried out by **Dr.M.Lavanya, (Regd. No. 321514205)** Dept of Kuzhanthai Maruthuvam, National Institute of Siddha, Tambaram sanatorium, Chennai under my guidance and supervision in partial fulfilment of regulation laid by The Tamil Nadu Dr.M.G.R Medical University, Chennai for the final M.D (Siddha), Branch IV – KUZHANTHAI MARUTHUVAM Examination to be held in OCTOBER – 2018. This dissertation work is not reprinted or reproduced from the previous dissertation work.

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CHAPTER I

INTRODUCTION

The Siddha system is considered as “Karpa viriksha” a desire tree as it holds all things experiential by man it deals with all existence however the medicinal dimension is considered as the first vital door to this mystic tradition and shines as its hallmark. It is the first system to emphasize health as the ideal perfected state of physical, psychological, social and spiritual component of a human being to prolong life

The siddha system depends on basic elements of earth, water, air, fire and space which forms a human body. Additionally, there are three doshas namely vatha (Air), pitha (bile), kapha (phlegm) are the fundamental principles which exists in all the cells regulating all the functions in our body and maintaining the balance in the physical, emotional and mental spheres.

Siddhars laid the foundation of this medical system. Among them Eighteen siddhars were said to contribute towards the development of this system. The father figure of siddha medicine, literature, grammar and above all of profound wisdom is the siddha Agasthiyar. The concept of siddhars were that a healthy soul can only be developed through healthy body.

Siddha system plays a major role in the field of paediatrics to cure disease. Because, childrens are the most vulnerable group in the society. They can be affected easily due to under developed immune system and they are exposed to several pathogen from surroundings. Many siddhars have been described paediatric disease in volumes and volumes of book like Balavagadam, Agathiyar pillai Tamil etc…ensured in order to cure diseases in childrens.

Mantham is one of the purakarana noigal (Diseases due to external factors) and commonly occurring disease in childrens. There are 21 types of mantham where listed in Balavagadam text book, Among those Kattu mantham occurs in children between the age of 1-3 years. It affects both male and female children with the symptoms of poor appetite, stomach pain/borborygmus, constipation sometimes with or without the symptoms of cough, fever and yawning. Kattu mantham may nearly be compared with Constipation of modern medicine.

Typically constipation develops during three stages of childhood namely during weaning in toddlers, during toilet training and in school age. The symptoms of constipation are abdominal pain, poor appetite, borborygmus, feeling sick. Child needs to go to the toilet but not passing stools and having painful micturition.

Epideomological studies says that the children affecting from constipation in childhood with the percentage of 0.7% and 29.6% (average of 12%). In the Out patient department of Ayothidoss Pandithar hospital, National Institute of Siddha around 2500 patients are visiting every day for treatment for various ailments. Among them, 3 - 5% of patients are in paediatric group and many patients are reporting with constipation problem.

In the text book of Balavagadam, authored by K.S.Murugesa mudhaliyar a sastric siddha medicine named “CHUKKU NEI” have been indicated for KATTU MANTHAM and “CHINNI THUVALAI” (external) also described in the same text book indicated for all types of mantham. These medicines were used only for 3 days.

The ingredients of this trial drug used commonly in various formulation and “CHUKKU NEI” and “CHINNI THUVALAI” is believed to be effective in the management of KATTU MANTHAM, but the scientific validation and proper clinical trial have not been done so far.

Hence the author selected “CHUKKU NEI” (internal) and “CHINNI THUVALAI” (external) in the treatment of KATTU MANTHAM as a dissertation study and discussed the topic on the basics of siddha concept as well as the modern aspect and about the treatment, prognosis and diatetic aspects.

CHAPTER II

2. AIMS AND OBJECTIVES:

Primary Aim and Objectives:

To evaluate the efficacy of Chukku nei as internal medicine and Chinni thuvalai as external in the management of Kattu mantham in Children under the following preclinical and clinical parameters

- Physicochemical Analysis, Phytochemical Analaysis, Bio chemical Analysis, Phamacological studies of trial drug
- Clinical trial study in Kattu mantham affected children.

Secondary objectives:

- To collect and review the ideas mentioned in the ancient Siddha literature about the disease Kattu mantham.
- To explore Definition, Etiology, Clinical features, Investigations, Diagnosis and treatment of Kattu mantham as laid down from various siddha literature.
- To explore the characteristics of kattu mantham with that of constipation as per siddha literature.

CHAPTER III

3. REVIEW OF LITERATURE

3.1 SIDDHA ASPECT

மாந்தம்

வேறுபெயர்கள்

மந்தம், அலசம், அலசகம் என பிள்ளைப் பிணி மருத்துவ நூலில் குறிப்பிடப்பட்டுள்ளது.

இய்ல

மந்த இயல்புடையது மாந்தம் எனப்படும். மந்தம் என்பது உருவ நிலையில்உடல்நிலையில் மந்தம். அருவநிலையில் அகக்கருவிகளாகிய மனம், புத்தி, சித்தம், அகங்காரம் ஆகிய அனைத்து அந்த கரணங்களிலும் மந்தம் என குழந்தை மருத்துவத்தில் கொடுக்கப்பட்டுள்ளது.

உண்ட உணவு செரியாமல் வயிற்றில் புளித்து வயிறு உப்பி இரைந்து மந்தத்தை உண்டாக்கி வாந்தியையும் கழிச்சலையும் உண்டாக்கி துன்பத்தை ஏற்படுத்தும் நோய் என பிள்ளைப் பிணிமருத்துவத்தில் குறிப்பிடப்பட்டுள்ளது.

நோய் வரும் பருவம்:

தாலப்பருவம், சப்பாணிப் பருவம், முத்தப் பருவம், வருகைப் பருவங்களில் உண்டாக்ககூடிய நோயாகும். குழந்தையின் முதல் ஆண்டில் இருந்து மூன்று ஆண்டுகள் வரை தொடரும் என **குழந்தை மருத்துவம்** மற்றும் **தன்வந்திரிகுழந்தை வாகடத்தில்** குறிப்பிடப்பட்டுள்ளளது.

இந்நோய் 3 மாதம் முதல் 12 வயது வரை வரக்கூடியது. பால் மட்டுமே குடிக்கும் பருவம், பாலும், சோறும் உண்ணும் பருவம், சோறு மட்டுமே உண்ணும் பருவம் ஆகிய முன்று பருவங்களிலும் மாந்தம் ஏற்படும் என **பிள்ளைப்பிணிமருத்துவத்தில்** குறிப்பிடப்பட்டுள்ளது.

நோய் வரும் வழி

- நீர்நிலைகளில் பழுத்து, உதிர்ந்த சருகுகள் விழுந்து அழுகியிருக்கும் நீரைக் குடித்தல்.
- எருமைப்பால், புளித்தஎருமைமோர், எருமை நெய். வாழைப்பழம், மாம்பழம், தேங்காய், இளநீர், கடலை, வெல்லம், காட்டுத் துவரை, மொச்சைக்கொட்டை, புளியங்கொட்டை, பருப்பு உருண்டை, மாவினால் செய்யப்பட்ட பொருட்கள், அதிரசம்,

வாயுப்பொருட்கள், சோறு இவைகளை அதிகமாக உண்ணல் முதலிய காரணங்களால் மாந்த நோய் உண்டாகும் என **குழந்தை மருத்துவம்** குறிப்பிடுகிறது.

- மந்தப் பொருளாகிய எருமைப்பால், நெய், வாழைப்பழம், மாம்பழம், கடலை, வெல்லம், மாமிசம், பருப்பு, உளுவை மீன், வரால் மீன், கெண்டை ஆகியவற்றை குழந்தைகள்உண்ணும்போது மாந்தநோய் உண்டாகும் என **தன்வந்திரி குழந்தை வாகடம்** கூறுகிறது.
- பாகற்காய், சுரை, உளுந்து, ஊன், பெரிய உளுவைமீன், வாளைமீன், பன்றிஇறைச்சி, விரால்மீன், கெண்டைமீன் ஆகிய ஆகாத பொருட்கள் உண்பதாலும், மாந்தநோய் உண்டாகும் என **பிள்ளைப்பிணி மருத்துவம்** குறிப்பிடுகிறது.
- மேலும் சோறு மட்டுமே உண்ணும் குழந்தையின் உணவு குற்றத்தினாலும் உணவின் வேறுபாட்டாலும் மாந்தம் ஏற்படும்.
- குழந்தையின் துய்மையற்ற தன்மை, சரியான நேரத்தில்சாப்பிடாது நேரந்தவறி சாப்பிடல், சுத்தமற்ற உணவுப் பொருட்களைச்சாப்பிடல், உடம்பில் போதிய ஊட்டச்சத்து இல்லாத நிலை ஆகிய காரணங்களினாலும் இப்பருவத்தில் இந்நோய் வரும்.
- உணவினால் மட்டுமின்றி செயலின் வேறுபாட்டாலும் மாந்த நோய் குழந்தையைத் தாக்கும். வறுமை, பசி, துயரம், மனக்கவலை, பயம், கோபம்,இச்சை போன்ற உணர்வுகளால் குழந்தையானது தாக்குறும் போது உணவுச்செரிக்கும் தன்மையில் மாறுபாடு நிகழ்ந்து மாந்தம் உண்டாகிறது என **பிள்ளைப்பிணி மருத்துவம்** கூறுகிறது.
- மேதிப்பால், நெய்,கதலிப்பழம், தேங்காய்,இளநீர், வெல்லம், புளித்த மோர், மாமிசம், கனிகள்,உளுந்து, மொச்சை, புளியங்கொட்டை, உளுவை, கெண்டைமீன், பாகல், சுரை முதலான வாயுப் பண்டங்களை பால் கொடுக்கும் மாதர்கள் மிகுதியாக உண்டால் அல்லது குழந்தைகள் அதிகமாக உண்டால் மாந்த நோய் உண்டாகும் என ஆவி அளிக்கும் அமுத முறை **சுருக்கத்தில்** குறிப்பிடப்பட்டுள்ளது

நோய் வகைகள்

குழந்தை மருத்துவத்தில் மாந்த நோய் 21 வகைகளாகப் பிரிக்கப்பட்டுள்ளது

1. வளி மாந்தம்
2. அழல் மாந்தம்
3. ஐயம் மாந்தம்
4. விடல் மாந்தம்
5. போர் மாந்தம்
6. வாலை மாந்தம்
7. சுரம் மாந்தம்
8. நீர் மாந்தம்
9. செரியா மாந்தம்
10. கட்டு மாந்தம்
11. பால் மாந்தம்

12. எரி மாந்தம்
13. துளை மாந்தம்
14. துலை மாந்தம்
15. கணம் மாந்தம்
16. வலிப்பு(இழுப்பு) மாந்தம்
17. சுழி மாந்தம்
18. முக்கு மாந்தம்
19. சந்நி மாந்தம்
20. ஊதல் மாந்தம்
21. வீக்கம் மாந்தம்

இது தவிர மேலும் 10வகை குறிப்பிடப்பட்டுள்ளன.

1. உப்பல் மாந்தம்
2. வாந்தி மாந்தம்
3. வறட்சி மாந்தம்
4. திட்டு மாந்தம்
5. உளை மாந்தம்
6. அக்கரம் மாந்தம்
7. பேய் மாந்தம்
8. நீர்கணம் மாந்தம்
9. தோடம் மாந்தம்
10. கருப்பம் மாந்தம்

எனவும் மற்றொரு வகைப்பாட்டின் படி, எண்வகை மாந்தம் கீழ்க்கண்ட வகைகள் கொடுக்கப்பட்டுள்ளது.

1. பொது மாந்தம்
2. செரியா மாந்தம்
3. தலை மாந்தம்
4. போர் மாந்தம்
5. கட்டு மாந்தம்
6. விட மாந்தம்
7. நீர் மாந்தம்
8. சுழி மாந்தம்

தன்வந்திரி பாலவாகடத்தில் மாந்தநோய் 21 வகைகளாக வகைப்படுத்தப்பட்டுள்ளது

1. அழல் மாந்தம்
2. ஊதல் மாந்தம்
3. எரி மாந்தம்
4. ஐயம் மாந்தம்
5. கணம் மாந்தம்

6. சந்நி மாந்தம்
7. சுரம் மாந்தம்
8. சுரி மாந்தம்
9. செரியாமை மாந்தம்
10. தலை மாந்தம்
11. துலை மாந்தம்
12. நீர் மாந்தம்
13. பால் மாந்தம்
14. போர் மாந்தம்
15. முக்கு மாந்தம்
16. வலிப்பு மாந்தம்
17. வளி மாந்தம்
18. வாலை மாந்தம்
19. விடம் மாந்தம்
20. வீக்கம் மாந்தம்

அனுபவ வைத்திய தேவரகசியத்தில் 8 வகைகள்:

1. செரியா மாந்தம்
2. பீர் மாந்தம்
3. சுர மாந்தம்
4. வி‘ மாந்தம்
5. சுழி மாந்தம்
6. ஊது மாந்தம்
7. நீர் மாந்தம்
8. தலை மாந்தம்

மதலை நோய் நூலில் மாந்தம்˙13 வகைகளாகப் பிரிக்கப்பட்டுள்ளது. (கும்ப முனி பாலவாகடம்)

“தோன்றிய வாதபித்தம்சொல்லிய சிலெற்ப மாந்தம்
ஊன்றியயதடுக்கு மாந்தம் விச மாந்தம் போர் மாந்தமதான்
கன்றியபால் மாந்தம் வன்கப பொது மாந்தம் பின்
வந்திடும்வினையாம் சன்னிவலி சர்த்தி பதிமூன்றாதாமே”

அவையாவன:

1. வாத மாந்தம்
2. பித்த மாந்தம்
3. சிலேற்பன மாந்தம்
4. நடுக்கு மாந்தம்
5. வி‘ மாந்தம்

6. போர் மாந்தம்
7. பால் மாந்தம்
8. வன்கப மாந்தம்
9. பொது மாந்தம்
10. வினை மாந்தம்
11. சன்னி மாந்தம்
12. வலி மாந்தம்
13. சாத்தி மாந்தம்

பிள்ளைப்பிணி மருத்துவம் :

Definition:

Indigested food in the stomach causes abdominal distension and manifests as Mantha Noi with vomiting and diarrhoea.

"மந்தமது வரலாறு சொல்லக் கேளீர்
மாதரோடு பாலகரு மருந்துந் தீனி
சேர்ந்ததொரு பால்தனிலே விசந்தான் கொண்டு
சிறுவருக்கு உதரத்தில் மந்தம் பற்றி
ஊர்த்தெழுந்த திரையினால் விரணங்கொண்டு
உள் விரணம் பல நோவு உறவ தாகி
சார்ந்த மலம் சிக்கியதில் தோச முண்டாய்
தானெழும்பும் மாந்தவகை சாற்று வேனே"

--பிள்ளை பிணி மருத்துவம்

The above verse states that Mantham occurs in children due the diet taken by the mother and the child, which causes indigestion and other related diseases. According to the Pillai Pini Maruthuvantext, Mantham occurs from the age of 3 months to 12 years in children particularly while child having breast milk (Exclusive Breast Feeding), then weaning period during which both milk and solid foods were given and later stage where the child given solid feeds (late weaning period).

During the period of exclusive breast feeding if the mother takes food which is not easily digestable in large amounts.The child becomes affected by Mantha Noi due to the intake of mother's devitalized milk. The psychological feelings of the mother also affects the quality of milk given to the child.

During the weaning period, due to the diet taken by both the mother and the child causes Mantha Noi. The psychosomatic feelings of mother like hunger, poverty, anger, fear, desire affects the efficacy of the milk fed to the child in this period.

During the late weaning period, the disease occurs mainly due to the improper food habits of children like taking not easily digestable foods, taking cleanless foods, taking irregular meal and taking imbalanced diet. Malnourished children are also affected by Mantham.

பிள்ளைப்பிணி மருத்துவம் பாகம் 2ல் மாந்தத்தின் வகைகள்- 53

In Pillai Pini Maruthuvam part 2 (Types 43)

1. Adai Mantham
2. Atcha Akkara Mantham
3. Azhal Mantham
4. Allu Mantham
5. Eluppu Mantham
6. Uppal Mantham
7. Uppu Mantham
8. Ulai Mnatham
9. Oothu Mantham
10. Eri Mantham
11. Iya Mantham
12. Kattu Mantham
13. Kana Mantham
14. Karppa Mantham
15. Kanai Mantham
16. Kal Mantham
17. Kazhi Mantham
18. Sakthi Mantham
19. Sanni Mantham
20. Sanni Bhatha Mantham
21. Sura Mantham
22. Suzhi Mantham
23. Seriya Mantham
24. Thalai Mantham

25. Thittu Mantham
26. Neer kana Mantham
27. Thulai Mantham
28. Neer Mantham
29. Pal Mantham
30. Pul Mantham
31. Bethi Mantham
32. Pei Mantham
33. Por Mantham
34. Maladi Mantham
35. Mukku Mantham
36. Valippu Mantham
37. Vali Mantham
38. Varatchi Mantham
39. Vanthi Mantham
40. Val Mantham
41. Vida Mantham
42. Thoda Mantham
43. Veekka Manthamare described.

43 வகை மாந்தங்கள்குறிகுணங்களுடன் காணப்படுகின்றன.

மீதமுள்ள10 மாந்தங்கள்பெயரளவில் மட்டும் வகைப்படுத்தப்பட்டுள்ளது.

குழந்தை மருத்துவத்தில் மாந்தத்தின் பொது குறிகுணங்கள்:

- குழந்தையின் உடம்பு சோர்ந்து இருத்தல்
- உடம்பு நோதல்
- மிகுதியான வியர்வை உண்டாதல்
- சுறுசுறுப்பாகஇல்லாமல் கண்விழி சிவந்திருத்தல்
- கண்கள் குழி விழுந்து காணல்
- முகம் வெளுத்து ஒரு வகை மங்கிய ஒளி காணல்
- குரல்தளர்ந்து வாய்உலர்ந்துகாணல்
- ஆடிக்கடி வாந்தி ஏற்படல்
- புசிஇன்மைகாணல்
- சீதமும் மலமுமாகவும், கெட்டுபோன பால் போவுலம், தண்ணீர் போலவும் பல நிறமாக பேதியாதல்
- கை கால்கள் சூடு இல்லாமல் குளிர்ந்து காணல்

கட்டு மாந்தக் குறிகுணம்

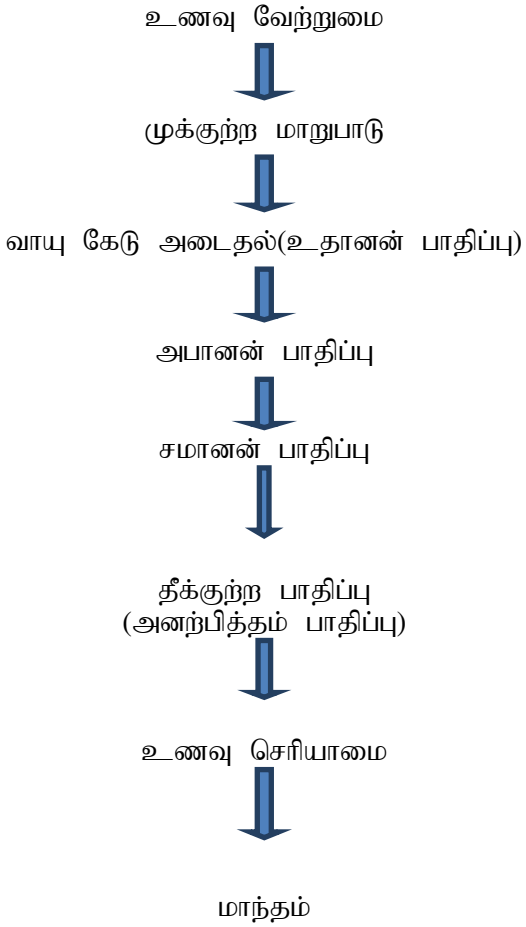
“தாயார் முலையில் வாய்வைத்துச்
சற்றே யுண்ணும் திகைத்திருக்கும்
ஓயா தழுகை சிற்றிருமல்
உள்ளே சுரமு மிகவுண்டாம்
சேயா மலமுஞ் சலங்கட்டிச்
சிக்கப் பண்ணும் பசியில்லை
மாயா மசக்கு மிதுகட்டு
மாந்த மென்று வகுத்தனரே”

-பாலவாகடம்

குறிகுணம்

1. மலம் சலம் கட்டுபடும்
2. சற்றே பாலுண்ணும்
3. பசியின்மை
4. சுரம்
5. கொட்டாவி
6. சிற்றிருமல்

முக்குற்ற வேறுபாடு



முக்குற்ற நிலைகள்:

i. Vali:

Site of vadham in body : வாதம் வாழுமிடம்

Abaanan, faces idakalai, below the umblical region, spermatic cord, pelvic bones, skin, nerve plexus, joints, hair follicle, muscle, alimentary tract, bones, ear and thighs.

மேலும்:

"அறிந்திடும் வாத மடங்கு மலத்தினில்"-திருமூலர்

"நாமென்ற வாதத்துக் கிருப்பிடமெ கேளாய்
நாபிக்குக் கீழென்று நவில லாகும்"-யூகி முனிவர்.

என்பதால்மலமும், நாபிக்கு கீழிடமும்வாதமிருக்குமிடங்கள்என கொள்ளலாம்

சித்தமருத்துவாங்கசுருக்கம்(ப.எண்.139)

Vadham consists of 10 types

1. Praanan: (Uyirkaal)

This controls knowledge, mind and five sense organs, which are useful for breathing and digestion.

2. Abaaban: (Keezh nokkung kaal)

This is responsible for all down ward movement such as passing urine, stools, semen, and menstrual flow. Abaanan vayu is affected in Kattu mantham due to constipation

3. Samaanan: (Nadukkaal)

This aids in proper digestion and controls other vayus. In Kattu mantham, this vayu is altered leading to poor appetite and cannot control the other vayus.

4. Viyaanan: (Paravukaal)

This is responsible for all movements of all parts of the body and distribution of saaram. This vayu is affected in Kattu mantham because of decreased activity due to symptoms like constipation.

5. Uthaanan: (Mel Nokkung kaal)

Responsible for all upward movementssuch as vomiting and nausea.It distributes the saaram equally to all tissues.It is affected in Kattu mantham because unequal distribution of saaram and presence of cough

6.Naagan:

Responsible for opening and closure of eye lids

7. **Koorman:**

Responsible for vision and yawning. .

8. Kirukaran:

This is responsible for salivation, nasal secretion, sneeze, cough and maintains the appetite. In Kattu mantham, this vayu is affected due to presence of cough and poor appetite.

9. Devathatthan:

This is responsible for tiredness (Lazziness), anger and emotional expression. This vayu is deranged in Kattu mantham because some patient had tiredness.

10. Dhananjeyan:

It produces swelling of the body after death. It escapes on the third day after death bursting out of the cranium.

சித்த மருத்துவாங்க சுருக்கம்(ப.எண்.142 - 149)

ii. Azhal:

Sites of pitham in body:

Pinkalai, praanavayu, urinary bladder, moolakkini, heart, head, umblical region, stomach, sweat, saliva, blood, saaram, eyes and skin.

"பிரிந்திடும் பித்தம் பேராம் சலத்தினில்" - திருமூலர்

"போமென்றபித்தத்துக் கிருப்பிடமேகேளாய்

பேரானகண்டத்தின் கீழே தாகும்"-யூகிமுனிவர்

கூறியிருப்பதனால் சிறுநீரும், கண்டத்தின்கீழிடமும் பித்தம் இருப்பிடமாகும்.

சித்த மருத்துவாங்க சுருக்கம்(ப.எண்.153)

Pitham consists of 5 types

1. Anal pitham:

It promotes appetite and helps in digestion. In Kattu mantham, it as affected due to presence of poor appetite.

2. Ranjagam:

It gives colour to the blood. In Kattu mantham, some children are anaemic.

3. Saadhagam:

It is important for day today activities with the help of mind and brain.

4. Praasagam:

It gives complexion to skin.

5. Aalosagam:

It brightens eyes and responsible for clear vision.

-சித்த மருத்துவாங்க சுருக்கம்(ப.எண்.155-157)

iii. Iyam:

Sites of Kabam in body:

Kabam (or) kapham is located in sammanavayu suzhumunai, sperm, head, tongue, uvula, fat, bone marrow, blood, nose, chest, nerve, bone, brain, large intestine, eyes, and joints and also present in throat, stomach and pancreas.

-சித்த மருத்துவாங்க சுருக்கம் (ப.எண்.158)

Kabam consists of five types

1. Avalambagam:

It lies in the lungs. It controls the heart and other four kabams.

In Kattu mantham, it is dearranged due to presence ofcough.

2. Kilethagam:

It lies in the stomach and gives moisture to food material and also helps for digestion. In this disease, it is affected because of thepoor appetite present in children.

3. Pothagam:

It lies in tongue and responsible for taste sensation.

4. Tharpagam:

It is present in the head and responsible for coolness of both eyes.

5. Santheegam:

It is present in joints. Responsible for lubrication and free movements of joints.

- சித்த மருத்துவாங்க சுருக்கம்(ப.எண்.161 - 163)

PINIYARI MURAIMAI: (DIAGNOSIS)

Piniyari muraimai is a method of diagnosing a disease. The way of diagnosis is very important to the physician who deal the disease, because of that only he or she can pont out the cause of disease.

இதனையே திருவள்ளுவர் திருக்குறளில் பின்வருமாறு கூறுகிறார்

“நோய்நாடி நோய்முத னாடியது தணிக்கும்

வாய்நாடி வாய்ப்பச்செயல்” – திருக்குறள்

Siddha system has a very unique method for diagnosis. This is based upon three principles.

1. Poriyaal arithal (Inspection)
2. Pulanaal arithal (Palpation)
3. Vinaathal (Interrogation)

I. Poriyaal arithal:

Porigal means the five sense organs. These are eyes, ears, nose, tongue and skin. Poriyaal arithal is examining the five sense orgn of the patient by the five sense organ of the physician.

In kattu mantham,

Mei (skin)	-	Normal
Vaai (Tongue)	-	Normal
Kann (Eye)	-	Normal
Mookku (Nose)	-	Normal
Sevi (Ear)	-	Normal

II. Pulanaal arithal:

Pulan means sense of perception from the five sense ongans.That means understanding by the sense objects.

In Kattu mantham,

Ooru (sensation)	-	Normal
Oosai (sound)	-	Normal
Oli (vision)	-	Normal
Suvai (Taste)	-	Normal
Naatram (smell)	-	Normal

III. Vinaathal:

Vinaathal means the physician should know about the patients name, age, occupation, family history, socio-economic status, diet and habits, complaints, relevant to disease in his family by asking questions.

Ezhu udar kattugal and Ennvagai thervugal also used for diagnosing a disease in Siddha system

Ezhu udar kattugal:

1. Saaram
2. Senneer
3. Oonn
4. Kozhuppu
5. Enbu
6. Moolai
7. Sukkilam/suronitham

When the seven udar kattugal increase or decrease from the normal level, the normal functions of the body will be affected.

In Kattu mantham.

a. Saaram : Deranged due to poor appetite causing tiredness.
b. Senneer : Deranged in some patient with nutritional anaemia.
c. Oonn : Normal
d. Kozhuppu : Normal
e. Enbu : Normal
f. Moolai : Normal.
g. Sukkilam/ Suronitham : Normal

The diagnostic value of Enn Vagai thervugal is specific to Siddha system of medicine Enn vagai thervugal are:

1. Naadi (Uyir thathu)
2. Sparisam (Touch feel sensation)
3. Naa (Tongue)
4. Niram (Colour of the skin)
5. Mozhi (Quality and character of speech)
6. Vizhi (Eye)
7. Malam (Stools)
8. Moothiram (Urine)

Naadi (Uyir thathu) :

Envagai thervugal is the basic diagnostic principles and the uniqueness of the siddha system of medicine. The following lines are said about this.

"மெய்க்குறி நிறந்தொனி விழி
நாவிருமலம் கைக்குறி"

-சித்த மருத்துவாங்க சுருக்கம்[5](ப.எண்.483)

Otherwise known as uyir thathu, is the principle method for diagnosis in siddha system. The naadi indicates the status of the body thathus and whether the body is normal or abnormal. It is responsible for existence of life in the physical body. It is said in literatures as

"உடலில் உயிர்தரித்திருப்பதற்கு காரணமான சக்தி எதுவோ அதுவே "தாது அல்லது நாடி" எனப்படும்.

"நாடிப்பரிசம் நாநிறம் மொழிவிழி
மலம்மூத்திரமிவை மருத்துவ ராயுதம்"

- நோய் நாடல்நோய் முதனாடல்[6](ப.எண். 270)

In childrens the naadi nadai is not clearly seen. This is indicated by following lines,

"கொண்டிடவே கயரோகி காசரோகி
குறிப்பாகச் சிற்றின்பம் செய்த பேர்கள்
அண்டிடவே தரித்திரர்கள் விருத்**தர் பாலர்**
அன்பாகத் தண்ணீரில் மூழ்கினோர்கள்
கொண்டிடவே இவர்களது உறுப்பின் தாது
கூறவே முடியாது எவர்க்குக் கிட்டும்"

- நோய்நாடல் நோய் முதனாடல் (ப.எண்:171).

b) Sparisam: (Touch feel sensation)

Identify the heat or coldness of the body, pain and skin nature (soft or hard)

In kattu mantham,

- It may be hot due to fever.
- It may be cold due to sweating.

c) Naa: (Tongue)

It is noted for colour of the tongue local lesion (ulceration, redness), coating deposition of tongue and dryness of the tongue.

d) Niram: (Colour of skin)

Colour of skin, conjunctiva, teeth, tongue, nail bed and hair are noted In Kattu mantham,

- Conjunctiva, nail bed may be pale due to nutritional anaemia

e) Mozhi : (Quality and character of speech)

Observation of speech and voice. This is said in Agasthiar vallathi as

"வார்த்தையைப் பார்"

In Kattu mantham normal voice is present.

f) Vizhi : (Eye)

By this examination, colour of eye (redness, pallor) protrusion, tears, excreta of eye, disease of eyes are noted. In Kattu mantham, the eyes of Some patients have pallor of lower eyelid due to nutritional anaemia.

g) Malam : (stools)

Consistency of stool, smell, frequency of defeacation, constipation, quantity of stool are noted. In Kattu mantham, patient have hard pellets like stools with decreased frequency.

h) Moothiram : (Urine)

Colour of urine (yellow, black, white copper colour, mixed colour. Then smell of urine (smell of fire, honey, sweet odours, fruity odour) frothy or not, frequency of urination and quantity of urine are noted.

In Kattu mantham, there will be normal straw yellow colour of urine with decreased frequency of urine.

Neer kuri and Nei kuri:

This urine examination is unique in Siddha system of Medicine

நீர்க்குறி:-

"அருந்து மாறிரதமும் அவிரோதமதாய்
அகல் அலர்தல் அகாலவூன் தவிர்ந்தழற்
குற்றளவருந்தி உறங்கி வைகறை
ஆடிகடகலசத் தாவியே காது பெய்

தொருமுகூர்த்தக் கலைக்குட்படு நீரின்
நிறக்குறி நெய்க்குறி நிறமித்தல் கடனே''

-நோய் நாடல்நோய் முதனாடல்(ப.எண். 282)

Collection of sample urine:-

The patient must take well cooked food in the previous day. Food intake should be taken at correct time and avoid excessive intake. The urine is collected on the dawn of the next day in a pure glass container and closed immediately to prevent contamination. This specimen must be examined with in one and half hours from the collection.

நெய்க்குறி:-

''நிறக்குறிக் குரைத்த நிருமாண நீரிற்
சிறக்க வெண்ணெய்யோர் சிறுதுளி நடு விடுத்
தென்றுறத் திறந்தொலி ஏகாதமைத்ததி
னின்றதிவலை போம் நெறி விழியறிவும்
சென்றது புகலுந்செய்தியை யுணரே''

- நோய் நாடல்நோய் முதனாடல்(ப.எண். 298)

A drop of gingelly oil is dropped on a wide glass vessel containing the urine to be tested which is kept under sunlight in a calm place. The derangement of three dhoshas can be diagnosed by the mode of spread of gingelly oil on the surface of urine.

In Kattu mantham the results of nei kuri is snake like oil floating on urine in some patients and ring like structure in some patients.

MARUTHUVAM:

The treatment in siddha medicine is aimed at keeping the Mukkutram in the state of equilibrium.
i.e,

- To bring down highly vitiated vatham to normal level
- To bring down Vitiated pitham to normal level
- To bring down Vitiated kabam due to vitiated vatham to normal level.
- To strengthen the seven udar kattugal and maintains to normal level.

Keeping in mind the need for bringing out an effective therapy for Kattu mantham with the Chukku nei along with Chinni thuvalai as external therapy.

Line of treatment:

Siddha treatment is not only for to cure the disease but also teaches prevention and rejuvenation concepts. Saint Thiruvalluvar says about the duty of a physician as follows

"நோய்நாடி நோய்முத னாடியது தணிக்கும்
வாய்நாடி வாய்ப்பச்செயல்"

– திருக்குறள்

"உற்றான ளவும் பிணியளவுங் காலமுங்
கற்றான் கருதிச் செயல்" – திருக்குறள்.

From the above verse, it is essential to know the etiology, the nature of patients, severity of the illness, the seasons and the time of occurrence the disease must be observed clearly.

Line of treatment is as follows：

1. Kaappu (prevention)
2. Neekkam (Treatment)
3. Niraivu (Restoration)

1. Kaappu: (Prevention)

Prevention is the main aim of siddha system. Siddhars have described general preventive measures and special measures.

Especially in Balavagadam, special preventive measures said for prevention of disease of the child. It starts from the conception and goes on the child grows up in intra uterine life and after delivery. ie diet of pregnant women, her habits, medicine to take in every month of pregnancy, her psychological conditions and surroundings.

2. Neekkam: (Treatment)

The aim of treatment is based on

- To bring the three thodams into normal equilibrium state.

- To treat the patients according to the symptoms by the trial medicines Chukku nei as internal medicine and Chinni thuvalai as external therapy.

Anupanam in Siddha system :

"அனுபானத்தாலே யவழ்தம் பலிக்கும்,
இனிதான சுக்கு கன்னல் இஞ்சி – பினுமுதகால்
கோமேயம் பால் முலைப்பால் கோநெய் தேன் வெற்றிலை நீர்:,
ஆழிதை யாராய்ந்து செய்யலாம்"

தேரையர் வெண்பா

Siddha system considers anupanam as in important. It is otherwise known as "Thunai marunthu", it can be translated as vehicle, adjuvant and supporting to drug therapy. Without anupanam, success in the treatment is mostly not possible.

Pathiyam in Siddha system :

During the course of treatment, the patients were advised to follow certain restrictions regarding diet and physical activities. This type of medical advice termed as pathiyam. Importance of pathiyam is said by Siddhars Theraiyar as follows,

"பத்தியத்தினாலே பலனுண்டாகும் மருந்து
பத்தியங்கள் போனால் பலன் போகும் - பத்தியத்தில்
பத்தியமே வெற்றிதரும் பண்டிதர்க்கு ஆதலினால்
பத்தியமே உத்தியென்று பார்" - தேரையர் வெண்பா.

The patient with Kattu mantham is advised to avoid spicy and hot food , contaminated water ,junk foods .

3. Niraivu: (Restoration)

- Reassurance of disease recovery was given to all patients.
- All the patients are advised to prepare for lifestyle changes that provides a disease free life.

Diet:

Siddhars advise the diet regimens for Kattu mantham patients. They are explained below:

“கத்திரி பேய்புடல வரை யிருபாகல் பருங்காளா கண்டகாரி
அத்திக் காய்களும் வருக்கைமாபயற்றை கரையால் பீர்க்கரும் பிஞ்சுவேர்
மொய்த்த சூரணங் கதலித் தண்டுகளைப் பூமுளங்கி முருக்கரும்பும்
அத்தி பூசணிக் காயருள்ளி வள்ளியுங் கபத்தோர்க் காணமாமே”

பதார்த்த குண சிந்தாமணி.

“வேளை மணத்தக்காளி மென்சீதை சக்கரவர்த்தி
பீளை வசலை சுக்கு பெண்கணங்கள் - வேளையில்
செந்தளிர் களைக்கீரை செய்வர் கபதேகர் நிதம்
வந்தளியுணத்தான் மகிழ்ந்து”

- பதார்த்த குண சிந்தாமணி.

காய்கறிகள்:-

- கத்தரி
- பேய்புடல்
- அவரை
- கண்டங்கத்திரி
- அத்திக்காய்
- பீர்க்கு
- வாழைத்தண்டு
- முருங்கை
- பாகல்
- பூசணி
- முள்ளங்கி

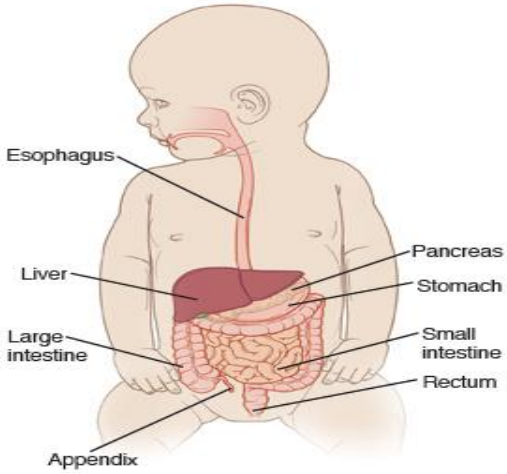
கீரைகள்:-

- மணத்தக்காளி
- சிறுகண்பீளை
- வசலை
- சிறுகீரை
- பொன்னாங்கன்னி
- சக்கரவர்த்தி கீரை
- சுக்கு கீரை ஆகியவைகளை உணவில் சேர்த்துக்கொள்ளவேண்டும்.

3.2. MODERN ASPECTS

GASTROINTESTINAL TRACT:

The Gastrointestinal tract is the pathway were food passes from the mouth, through the esophagus, stomach, small and large intestine within where the nutrients are extracted for the needs of the body. The residue then passes to the rectum where it is evacuated.



ANATOMY OF THE GASTROINTESTINAL TRACT:

The Esophagus:

The first part of the pathway of GIT is the esophagus, which guides food from the mouth, where it is prepared by chewing down to the stomach where it is stored.

The Stomach:

The stomach is both a storage space, holding as much as a quart and a half of ingested food, and a secretory organ that produces the gastric acid necessary for digestion However, the stomach does not absorb food. When food enters the stomach from the esophagus it remains for a short period while it is mixed with gastric acid. The stomach then by involuntary muscle contractions (peristalsis) empties the food gradually into the duodenum, the first part of the small intestine.

The small Intestine:

The small intestine consists of three parts: the duodenum, the jejunum and the ileum. In these three parts, certain digestive secretions are mixed with food, and the nutrients are absorbed into the blood stream

I.**The Duodenum:**

The duodenum treats the food it receives with bile from the liver and enzymes from the pancreas. It also adds liquid duodenal fluid that comes from the wall of the duodenum itself. The food, bile, enzymes and liquids brought together in the duodenum are then passed into the jejunum

II.**The Jejunum:**

The jejunum or second portion of the small intestine is approximately 10 feet long. It lies immediately behind the duodenum and continues the process of digestion, breaking down food into essential elements

III.The Ileum:

The ileum or third portion of the small intestine, like the jejunum, is about 10 feet long. It is here that a major part of the absorption of food products and liquids occurs. Waste products of the digestive process are passed from the small intestine or terminal ileum, into the large intestine, also known as the colon.

Large Intestine (colon):

The colon moves waste products through about four feet by the continuing process of undulating motions or peristalsis, which is common to all parts of the gastrointestinal tract. The primary function of the colon is to store waste products of digestion prior to evacuation. The colon absorbs small amounts of water and electrolytes.

COMMON GASTROINTESTINAL TRACT DISORDER

CONSTIPATION

DEFINITION

Constipation refers to bowel movements that are infrequent or hard to pass. The stool is often hard and dry. Constipation is a symptom, not a disease. Most commonly constipation is thought of as infrequent bowel movements, usually less than 3 stools per week. Children may have other complaints as well including

- Straining with bowel movements
- Excessive time needed to pass a bowel movement
- Abdominal pain
- Abdominal bloating
- Pain with bowel movements secondary to straining
- Hard or lumpy stool
- Sensation of incomplete evacuation

Newborns

- First meconium stool usually within the first 36 hours of birth in normal newborns
    - 90% pass stool within 24 hours
- This may happen later in preterm infants without underlying structural defects.
- First week of life, normal newborn has 4 stools per day, with some variability
    - Breastfed infants can stool with each feeding or only once every 7 to 10 days
    - Formula feed infants tend to stool more regularly than breastfeed infants
    - Soy formulas known to cause harder stools
    - Protein Hydrolysate and Elemental formulas associated with looser stools

Causes for Delayed passage of meconium

- Intestinal Obstruction / Anatomical Malformation
- Hirschsprung's Disease
- Meconium Ileus
- Functional Ileus (Prematurity, Sepsis)
- Small left colon
- Maternal Drugs
- Hypothyroidism

Normal Frequency of Bowel Movements

AGE	MEAN OF BOWEL MOVEMENTS PER WEEK	MEAN OF BOWEL MOVEMENTS PER DAY
0-3 MONTHS BREASTFED	5 TO 40	2.9
0-3 MONTHS FORMULA FED	5 TO 28	2.0
6-12 MONTHS	5 TO 28	1.8
1-3 YEARS	4 TO 21	1.4
>3 YEARS	3 TO 14	1.0

CONSTIPATION IN INFANTS AND TODDLERS:

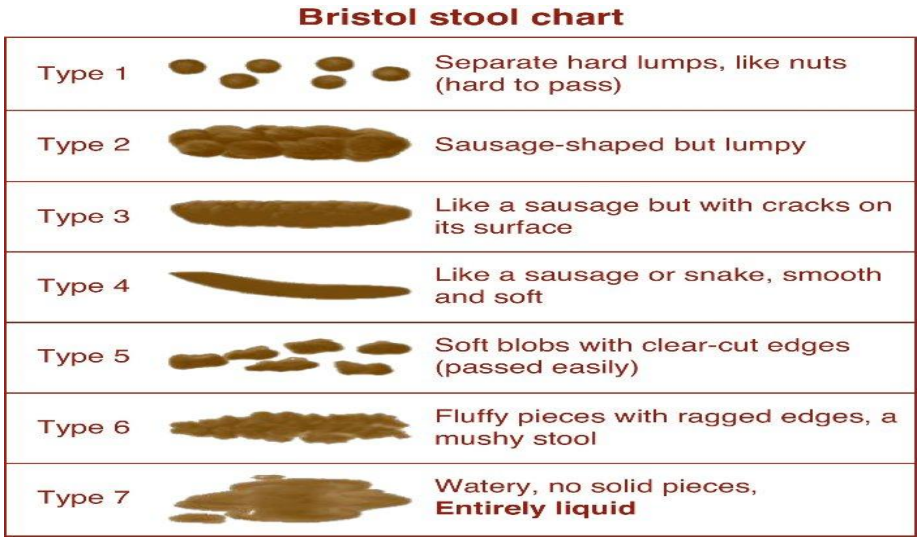
At least two of the following present for at least one month

- Two or fewer defecations per week
- At least one episode of incontinence after the acquisition of toileting skills
- History of excessive stool retention
- History of painful or hard bowel movements
- Presence of a large fecal mass in the rectum
- History of large-diameter stools that may obstruct the toilet

Symptoms

- Passing fewer than 3 stools per week
- Hard or small stools
- Abdominal distension
- Abdominal and Rectal pain
- Flatulence
- Loss of appetite, nausea and vomiting
- Lethargy

Chart no 3.2.1. Bristol Stool Chart



Chronic Constipation

- 3% of the visits to general pediatrics
- 25% of the visits to pediatrics G.I.

Epidemiology:

The prevalence of childhood constipation in the general population ranged from 0.7% to 29.6%.

FUNCTIONAL AND ORGANIC TYPE OF CONSTIPATION

Functional

Over 95% of constipated children have functional constipation. Functional: persistent, difficult, infrequent, or seemingly incomplete defecation without evidence of underlying structural or metabolic defect. Most commonly due to with-holding after a painful bowel movement, most commonly at three age periods, at introduction of cereals and solid foods,at toilet training and at start of school days.

Functional Constipation

Child has a painful bowel movement. When urge to have a bowel movement happens, the child consciously withholds stool by contracting their external anal sphincter and gluteal muscles. Eventually, the rectum habituates to the stimulus of the enlarging fecal mass, the urge to defecate subsides, and the retentive behaviour becomes almost second nature or subconscious can develop soiling (encopresis)

Organic

Accounts' for less than 5% of all constipation

- Anatomic malformations
- Metabolic causes
- Neuropathic conditions
- Intestinal nerve and muscle disorders
- Drugs
- Hypotonia
- Miscellaneous

CHRONIC CONSTIPATION:

Organic disorders are a major cause. A significant number of the children with chronic treatment-resistant constipation may have organic causes (slow colonic transit and outlet obstruction) and suggests new approaches to the management of children with chronic treatment-resistant constipation. Stool with holding presenting as a cause of non-epileptic seizures.

Chronic Constipation and food hypersensitivity

An increasing number of reports suggest a relationship between refractory chronic constipation and food allergy in children.

History

- Meconium passage
- Frequency of bowel movement
- Diet
- School/Travel
- Painful defecation
- Family history

Systemic Examination

- Inspection
    - Abnormal appearance/position/patency of anus
- Abdominal examination
    - Gross abdominal distension
    - Any abdominal mass

- Rectal examination
    - Anal sphincter tone
    - Presence of haemarrhoids
    - Any perianal irregularitiesincluding skin tag,anal fissures

Evaluate of History

- Meconium passage
- Frequency of bowel movement
- Diet
- School/Travel
- Painful defecation
- Family history

COMPLICATION

- Haemarrhoid
- Anal fissure
- Fecal impaction

INVESTIGATION

- Thyroid function test
- Plain abdominal X- rays are generally performed if bowel obstruction is suspected, may reveal extensive impacted fecal matter in the colon, and may confirm to rule out other causes of similar symptoms
- Colonoscopy may br performed if an abnormality in the colon like a tumor is suspected.
- Rarely ordered include Anorectal manometry,
- Anal sphincter electromyography
- Defecography

TREATMENT

The treatment of constipation should focus on the underlying cause if known.

- Fiber Supplements
- If Laxatives are used such as Milk of Magnesia or Polyethylene glycol are recommended as first line agents

- In case of Chronic constipation, Polyethylene glycol appears superior to Lactulose.
- Prokinetics may be used to increase Gastro intestinal motility

MANAGEMENT

The goals of treating constipation in childhood are to produce soft, painless stools and to prevent the re accumulation of faeces. These outcome are achieved through a combination of

- Education
- Dietary modification
- Maintenance
- Behavioural Modification

PREVENTION

Constipation is usually easier to prevent than to treat. Following the relief of constipation, maintainence with fluid intake and high fibre diet is recommended.

PROGNOSIS

Complication that can arise from constipation include haemorrhoids, aanal fissured, rectal prolapse, and fecal impaction.straining to pass stool may lead to haemorrhoids. In later stage of age abdomen may become distended, hard and diffusely tender.

DIET

- Mild constipation
    - Increase fluid intake
    - Increase fiber intake

Increase dietary fibers

- Beetroot
- Banana, Apple, Guava
- Spinach
- Green Leaf vegetables
- Almond
- Legumes

DIFFERENTIAL DIAGNOSIS

A) Hirschsprung's Disease

It is a congenital disease. Children with Hirschsprung's disease are missing the nerve cells (ganglion cells) within the wall of their colon or rectum. These cells are responsible for the normal wave-like motion of the bowel (peristalsis). When they are missing the stool stops and an obstruction occurs. The length of affected bowel varies. The most common transition point is in the upper rectum or the sigmoid colon.

Symptoms

- Vomiting and abdominal distention in newborn
- Chronic constipation
- More rarely diarrhea, fever, and distention (symptoms associated with enterocolitis – inflammation of the small intestine and colon).

B) Irritable bowel syndrome

Irritable bowel syndrome (IBS) is a disturbance of bowel function that includes symptoms of abdominal pain or discomfort and altered bowel habit (change in frequency or consistency) – chronic or recurrent diarrhea, constipation, or both in alternation. IBS comprises a group of functional bowel disorders.

Symptoms

- Start with bowel movements that occur more or less often than usual
- Start with stool that appears looser and more watery or harder and more lumpy than usual
- Improve with a bowel movement symptoms must occur at least once per week for at least 2 months.

COMPLICATION OF CONSTIPATION

- Haemarrhoids
- Rectal prolapse
- Anal fissure
- Fecal impaction

3.3. DRUG REVIEW

THE REVIEW OF INGREDIENTS OF CHUKKU NEI

INGREDIENTS:

- Chukku (Zingiber officinale)
- Citrarathai (Alpinia officinarum)
- Vetrilai (piper betel)
- Omum (Trachyspermum ammi)
- Murunga pattai (Moringa oleifera) - a mixture of 325 ml surasam
- Vembu nei (Azadirachta indica) - 325 ml

1. CHUKKU

Botanical Name : Zingiber officinale

English Name : Dried Ginger

Family : Zingiberaceae

Part used : Rhizome

ORGANOLEPTIC CHARACTER

Suvai **:** Karppu

Thanmai **:** Veppam

Pirivu **:** Kaarppu

பொது குணம்:

சூலைமந்தம் நெஞ்செரிப்பு தோடமேப பம்மழை

மூலம் இரைப்பிருமல் மூக்குநீர்-வாலகப

தோடமதி சாரந் தொடர்வாத குன்மநீர்த்

தோடம்ஆ மம்போக்குஞ் சுக்கு.

(அகத்தியர் குணவாகடம்)

CHEMICAL CONSTITUENTS:

- Camphene
- Phellandrene
- Zingiberine
- Cineol and Borneol
- Gingerol and shogoals
- Diterpenes
- Gingerglycolipids A,B,C
- An Oleoresin-Gingerin
- Resins and starch
- β-Sesquiphellandrene
- Gingerdiols, Gingerdiacetates.

ACTIONS:

- Carminative
- Stomachic
- Stimulant

PHARMACOLOGICAL ACTION

- Gastro protective
- Antioxidant
- Anti tussive
- Antiemetic
- Immunomodulatory

RECENT RESEARCH

A Review on Ginger – Gastroprotective Activity

Ginger and its constituent shows a vital role in ulcer prevention via increasing mucin secretion. Earlier finding have shown anti ulcer effects on ginger in experimental gastric model. Chief constituent of ginger such as gingerol, shogaols suppressed gastric contraction in situ and suppression by the shogoal was more intensive.

Journal of Pharmacognosy and Phytochemistry 2017, 6(3); 174-184 by Jyotsna Dhanik, Neelam Arya and Viveka Nand

Physiological and Pharmaceutical Effect of Ginger(Zingiber Officinale) As Avaluable Medicinal Plant

The active components of ginger is reported to stimulate digestion, absorption, relieves constipation and flatulence by increasing muscular activity in the digestive.

(European Journal of Experimental Biology, 2014, 4(1); 87-90 by Jalal Bayati Zadeh and Nasroallah Moradi Kor)

2. OMUM

Botanical Name	:	Trachyspermum ammi
English Name	:	The bishops weed
Family	:	Apiaceae
Parts used	:	Seeds

ORGANOLEPTIC CHARACTER

Suvai	:	Kaippu
Thanma	:	Veppam
Pirivu	:	Kaarppu

பொது குணம்

சீதசுரங் காசஞ் செரியாமந் தம்பொருமல்

பேதியிரைச் சல்கடுப்பு பேராமம் - ஓதிருமல்

பல்லொடுபல் மூலம் பகமிவைநோ யென்செயுமோ?

சொல்லொடுபோம் ஓமமெனச் சொல்.

(அகத்தியர் குணவாகடம்)

CHEMICAL CONSTITUENTS:

- Thymol
- P-cymene
- Gamma terpinene
- Beta pinene
- Terpinene

ACTIONS:

- Stomachic
- Antispasmodic
- Carminative
- Antiseptic
- Stimulant
- Tonic

PHARMACOLOGICAL ACTION

- Gastro protective
- Antioxidant
- Anti tussive
- Anti spasmodic
- Diuretic
- Anti tussive
- Anti pyretic

RECENT RESEARCH

Gastroprotecrive activity of ethanolic extract of trachyspermmum ammi fruit

The oral administration of ethanolic extract of ammi fruit exhibits antiulcer in the experimental ulcer model. The probable mechanism for its activity may be due to Anti secretory and Cytoprotective property

(International journal of pharma and bio science v1(1)2010 by S.Ramaswamy and S.Sengottu velu)

Gastroprotective activity of trachyspermum ammi against ethonolic induced gastric ulcer

Animals pretreated with hydroalcoholic extract of trachys.ammi at dose 250 mg/kg and 500mg/kg shows significant decreased in ulcer index and percentage ulcer production in all models.the results shows by reducing ulcerative lesion when compared to control group of animals.

(Journal of scientific research in pharmacy 2014, 3 (3) 96- 100 by Abdul Azeez, Mohammad Mansoor)

3. VETRILAI

Botanical Name	: Piper betel
English Name	: Betal leaf
Family	: Piperaceae
Part used	: Leaf

ORGANOLEPTIC CHARACTER

Suvai	: Viruvirupu, Kaarpu
Thanmai	: Veppam
Pirivu	: Kaarpu

பொது குணம்

ஐயம் அறுங்காண் அதன்காரங் கொண்டக்காற்

ஐபயச் சயித்தியம்போம் பைந்தொடியே!- மெய்யின்

கடியின் குணம் போகங் காரவெற்றி லைக்குப்

படியுமுர் தோடமிதைப் பார்.

(அகத்தியர் குணவாகடம்)

CHEMICAL CONSTITUENTS:

- Piperol A
- Piperol B
- Methyl piper betlol
- Eugenol
- Essential oil
- Starch
- Ethyl acetate.

ACTIONS:

- Carminative
- Stimulant
- Astringent
- Antiseptic

- Febrifuge
- Stomachic

PHARMACOLOGICAL ACTION

- Anti histaminic,
- Antioxidant,
- Gastroprotective effect

RECENT RESEARCH

Influence of benzene extract of Piper betel on delayed in small intestine transit by chlorpromazine involving calcium innervation in mice

It is reported that calcium is involved in the initiation of contraction of smooth muscle. It increases small intestinal motility through L type channel. Chlorpromazone blocks the calcium channel and smooth muscle relaxes by attenuating intestinal motility. The present study was to evaluate the influence of benzene extract of piper betel on small intestinal motility.

(International journey of current research and review www.ijcrr.com vol.01 issue 01)

Evaluation Of Anti Ulcerogenic Potential of Piper Betel Leaves Extract as An Adjuvant Theraphy With Omeprazole Against Stress Ulcer In Rat

(Pharmacologyonline 2:46-56 (2010) katedeshmukh et al)

Gastroprotectivity activity

The hot water piper betel leaves extract study shows that it can protect against indomethacin induced gastric ulceration due to its anti oxidant and mucin protecting property

(Journal Of Pharmacognosy And Phytochemistry By Pradhan D;et al ,2013)

4. CITRARATHTHAI

Botanical Name	:	Alpinia officinarum
English Name	:	Galangal
Family	:	Zingiberaceae
Parts used	:	Rhizome

ORGANOLEPTIC CHARACTER

Suvai	: Kaippu
Thanma	: Veppam
Pirivu	: Karppu

பொது குணம் :

தொண்டையிற்கட் டுங்கபத்தைத்த தூரத் துரத்திவிடும்
பண்டைச்சீ தத்தைப் பறக்கடிக்கும் - கெண்டைவிழி
மின்னே! கரப்பனைவே றாக்கும் பசிகொடுக்கும்
சொன்னோம் அரத்தைச் சுகம்.

(அகத்தியர் குணவாகடம்)

CHEMICAL CONSTITUENTS:

- Cineole
- Beta caryophyllene
- Methyl cinnammate
- Alpha terpenol
- Acetoxychavicol
- Essential oil
- Tannins,phenols,glycosides,carbohydrate,
- Galangin,alpinin
- Galangoisoflavanoid

ACTIONS:

- Expectorant
- Febrifuge
- Stomachic

PHARMACOLOGICAL ACTIONS

- Anti oxidant
- Carminative
- Anti pyretic
- Anti spasmodic
- Immuno modulator

RECENT RESEARCH

Alpinia officinarum : phytochemistry and pleiotropism

It has been reported that kaemjeride, kalangin and 7-1-phenyl hept 4ene one inhibit m-rna expression of tyrosinase and protein level of micropthalmia associated transcription factor.moreover 5 hydroxy 7-1-3-heptance has been noted to show anti emetic properties. The alcoholic effect of rhizome relieves stomach ache and treating cold.

(International Journal of Pharmaceutical And Phytopharmacological Research 2012, 2(2); 122-125 By Arti Dixit, Ankur Rohilla)

5. MURUNGAPATTAI

Botanical Name	:	Moringo oleifera
English Name	:	Drum stick
Family	:	Moringaceae
Part used	:	Bark

ORGANOLEPTIC CHARACTER

Suvai	:	Kaippu, Thuvarpu, Inippu
Thanmai	:	Thatpam
Pirivu	:	Karppu

பொது குணம் :

முருங்கைவேர்ப் பட்டைக்கு மூடு கபத்தோ

டொருஞ்குறாச் சன்னிகரம் ஓடும் - அருங்கனக,

வட்டைப் பொருமுலையாய்! வாய்வொடுவி டங்களுமேற்

பட்டைக்குப் போமே பறந்து,

CHEMICAL CONSTITUENTS:

- Pterygospermin
- Moringine
- Moringinine
- Beta sitosterol
- Glycosides

- Tannin
- Triterpenoids and steroids
- Moringic acid
- Niazinin A & B
- Campesterol
- Stigmasterol
- Aminoacid

ACTIONS:

- Antispasmodic
- Stimulant
- Expectorant
- Diuretic

PHARMACOLOGICAL ACTION

- Anti asthmatic
- Antispasmodic
- Antipyretic
- Antioxidant
- Diuretic
- Gastroulcer protective

RECENT RESEARCH

Clinical efficacy of Moringa oleifera Lam.stems bark in Urinary Tract Infection

(International scholary research notices vol 2014, Article id 196843 by Santosh Kumar Maurya and Anil kumar Singh)

Dietary effects of moringa oliefera leaf powder on growth gastro intestinal morphometry and blood liver metabolites in sprauge dawley rats

(Zvinorova Pl,et al. J Anim Physiol Anim Nutr(Berl) 2015 pubmed)

6.VEMBU NEI

Botanical Name : Azadirachta indica

English Name : Margosa tree

Family : Meliacea

Part used : Seed

ORGANOLEPTIC CHARACTER

Suvai : Kaippu

Thanmai : Veppam

Pirivu : Karppu

பொது குணம்

வாதம்போம் பித்தமிகும் மாறாக்கி ரந்தியொடு

மோதுகரப் பான்சிரங்கு முன்னிசிவும்-ஓதுடலின்

நாப்ப ணுறுசுரமு நாடுசன்னி யுந்தொலையும்

வேப்பநெய் யென்றொருக்கால் விள்ளு.

(அகத்தியர் குணவாகடம்)

CHEMICAL CONSTITUENTS:

- Azadirachtin
- Stigmasterol
- Campesterol
- Beta sitosterol
- Omega 6,9
- Triglycerides
- Palmitic acid,stearic acid
- Nimbin

ACTIONS:

- Stimulant
- Antiseptic
- Anthelmintic
- Antiperiodic
- Tonic

PHARMACOLOGICAL ACTION

- Inhibit gastic hyper acidity and ulcer

RECENT RESEARCH

Neem oil, bark and leaf extracts have been therapaeutically used as folk medicine to control leprosy, respiratory disorder, intestinal helminthiasis, constipation and also a general health promoter. It posses a pharmacological activities are Antifungal, Anti bacterial, Anti malarial, Anti ulcer and Antioxidant.

Neem oil nanoemulsions: characterization and antioxidant activity

(Rinaldi F, et al. J Enzyme inhib Med Chem 2017)

REVIEW OF INGREDIENTS OF CHINNI THUVALAI- EXTERNAL MEDICINE

Ingredients

- Chinni ilai (Acalypha fruticosa)
- Notchi ilai (Vitex negundo)
- Seenthil ilai (Tinospora cordifolia)
- Vembu ilai (Azadirachta indica)

1. NEEM

Botanical Name : Azadirachta indica
English Name : Margosa tree
Family : Meliaceae
Part used **:** Leaf

ORGANOLEPTIC CHARACTER

Suvai : Kaippu
Thanmai : Veppam
Pirivu : Karppu

பொது குணம்

கிருமிகுட்ட மாந்தங் கெடுவிடஞ்சு ரங்கள்

பொருமியம சூரிகையின் புண்கள் - ஒருமிக்க

நிம்பத் திலையிருக்க நீடுலகில் நீங்காமல்

கம்பத் திலையிருக்கக் காண்.

CHEMICAL CONSTITUENTS:

- Azadirachtin
- Nimbin and deazyl nimbin
- Salanin
- Melianol
- Nimbidin
- Nimbinin
- Azadirone

ACTIONS:

- Stimulant
- Anthelmintic

RECENT RESEARCH

Therapaeutic Role of Azadirachta indica (Neem) And Their Active Constituents in Diseases Prevention and Treatment

Neem oil, bark and leaf extracts have been therapaeutically used as folk medicine to control leprosy, respiratory disorder, intestinal helminthiasis, constipation and also a general health promoter. It posses a pharmacological activities are Antifungal, Anti bacterial, Anti malarial, Anti ulcer and Antioxidant. The study based on animal model established that neem and its chief constituents play private role in anticancer management through the modulation of various molecular pathway including p53, Pten, Nf-B, P13 K/Akt, Bcl-2 and VEGF. It is considered as safe medicinal plants and modulates the numerous biological process without any adverse effect.

(Evidence Based Complementary and Alternative Medicine 2016, 2016> PMC4791507)

2. NOTCHI

Botanical Name : Vitex negundo

English Name : Five leaved chaste tree

Family : Fabaeceae

Part used : Leaf

ORGANOLEPTIC CHARACTER

Suvai : Kaippu,Thuvarpu, Kaarppu

Thanmai : Veppam

Pirivu : Karppu

பொது குணம்

.....கர நொச்சிற் பட்டையது

துள்ளுசன்னி வாத மகற்றும்.....

CHEMICAL CONSTITUENTS:

- Negundoside
- Terpenoids
- Dimethoxy flavone
- Vitexilactone
- Vitexicarpin
- Vitricine
- Vitetrifolins

ACTIONS

- Alterative
- Vermifuge

RECENT RESEARCH

Phytochemical Constituents and Pharmacological Activity of Vitex Negundo Linn

It is large aromatic shrub.phytochemical investigation shows the predence of flavonoid,essential oil, ligands , glycoside and posses enormous pharmacological activity such as Antipyretic, Antioxidant, Anti tumour, Anti arthritic, Analgesic activity.

(Journal of Chemical and Pharmaceutical Research,2016,8(2);800-807 by Suganthi N.And Sonal Dubey)

3. .SEENTHIL

Botanical Name : Tinospora cordifolia

English Name : Heart leaved moon seed, Tinospora, Gulancha tinospora

Family : Menispermaceae

Part used : Leaves

ORGANOLEPTIC CHARACTER

Suvai : Kaippu

Thanmai : Veppam

Pirivu **:** Kaarppu

பொது குணம்

சீந்திற் கிழங்கருந்தத் தீபனமாம் மேகவகை

போந்தவுதி ரப்பித்தம் பொங்குசுர - மாந்தம்

அதிசாரம் வெய்யகணம் ஆம்பலநோ யோடே

கதிவிடமுங் கெட்டுவிடுங் காண

CHEMICAL CONSTITUENTS:

- Berberine
- Palmatine
- Phenylpropene disaccharides
- Cordifolioside,
- Asesqueterpene,
- Choline tinosporicacid
- Cordioside
- Lactone
- polysaccharides

ACTIONS:

- Alterative
- Demulcent

- Antiperiodic
- Stimulant
- Stomachic
- Tonic
- Mild diuretic

RECENT RESEARCH

Chemistry and medicinal properties of *Tinospora cordifolia* (guduchi)

The stem of *Tinospora cordifolia*is one of the constituents of several ayurvedic preparations used in general debility, dyspepsia, fever and urinary diseases. The stem is bitter, stomachic, diuretic, stimulates bile secretion, causes constipation, allays thirst, burning sensation, vomiting, enriches the blood and cure.s jaundice. The extract of its stem is useful in skin diseases. The root and stem of T. cordifolia are prescribed in combination with other drugs as an anti-dote to snake bite and scorpion stingDry barks of T. cordifolia has Anti-spasmodic, Antipyretic, Anti-allergic, Anti-inflammatory and Anti-leprotic properties.

(Indian Journal of Pharmacology 2003; 35: 83-91 educationaforum)

Tinospora cordifolia a phyto pharmacological revirew

The notable properties are Anti spasmodic, Anti diabetic, Anti inflammatory, Anti oxidant, Hepatoprotective and Immunomodulatory.

(International Journal Of Pharmaceutical Science And Research 2017 By Garish Joshi And Rajandeep Kaur)

Enhance intestinal permeability of tinospora cordifolia extract through nano emulsion formulation in in vitro and ex- vivo studies

(Journal of nanopharmaceutics and drug delivery vol 2 num 3 sep 2014,pp,209 – 218 (10) by Kumar Arun, Sanjay)

4. CHINNI

Botanical Name : Acalypha fruticosa

Telugu Name : chinni

Family : Euphorbiaceae

Part usd : Leaf

ORGANOLEPTIC CHARACTER

Suvai : Kaippu

Thanmai : Veppam

Pirivu : Karppu

பொது குணம்

கடிவிடமுங் காணாக் கடிவிடமும் மாதர்

இடுவிடமும் ஓடுமிது வன்னி – நெடியவிழிக்

கன்னிகையே மேகங் கணக்காய்ச்சல் மாந்தமும்போஞ்

சின்னி யிலைக்குத் தெறித்து

CHEMICAL CONSTITUENTS:

- Isocaryophyllene
- Beta caryophyllene
- Alpha humulene
- Caryophyllene oxide
- Trans phytol

ACTIONS:

- Alterative
- Stomachic

RECENT RESEARCH

Bioactive and chemical characterization of acalypha fruticosa forssk.

Acalypha fruticosa is traditionally used as a cure for stomach ache, dyspepsia, rheumatism, dermatitis, and swellings of the body.the present study to endeavors to provide a phytochemical and biological evaluation of plant. By column chromatographic separation four compounds were isolated namely beta d glucopyranoside, Acalyphin, Apigenin, kaempferol 3-o-rutinoside were subjected to assay Anti inflammatory and Cytological activity. It promosing Anti inflammatory activity.

(Saudi Pharmaceutical Journal Vol 25, issue 1, Jan 2017 Pg 104-109 by Ghada Ahmed Fawzy)

Evaluation of Anti Epileptic Activity of Chloroform Extract of Acalypha Fruticosa In Mice

(Pharmacognosy Research 2014 vol 6 issue 2 pg 108-112 by Sumalatha Govindu, Sreedevi Adikay)

CHAPTER IV

4. MATERIALS AND METHODS

Kattu Mantham is one of the common GIT disorder in children. In Ayothidoss pandithar Hospital NIS OPD 3-5% of cases are approaching Kuzhandhai Maruthuvam department daily with the Symptoms of Kattu Mantham. Hence, it was proposed to study about the disease. A protocol was prepared and submitted before IEC of National Institute of Siddha. The IEC approval was obtained No: NIS/IEC/18-14/20-18-26-08-2014. The trial was registered in Clinical trial Registry of India with RegNo. CTRI/ 2016/04/ 006818. After obtaining approval from the committee, the clinical study on Kattu mantham(Constipation) in children with drug Chukku nei (internal) and Chinni thuvalai (external) are carried out as per the protocol.

Physicochemical analysis and pharmacological activity studies of Chukku nei (internal) were conducted in Noble Research Solutions, Chennai.

After finishing the pharmacological Activity studies, 30 cases were selected from the OPD & IPD of Kuzhandhai Maruthuvam Department, National Institute of Siddha. Those meeting the inclusion and exclusion criteria they were treated with the trial drug with Chukku nei (internal) and Chinni thuvalai (external)and observed for prognosis clinicaly.

PREPARATION OF CHUKKU NEI

COLLECTION OF RAW DRUGS

The required drugs were purchased from Ramaswamy Chettiyar country drug shop, kandha swamy kovil street Paris, Chennai.

AUTHENTICATION

Raw drugs were authenticated by the Medicinal Botanist in National Institute of Siddha, Chennai. The test drug Chukku nei was prepared at Gunapadam lab, National Institute of Siddha.Chennai-47

Preparation

INGREDIENTS:

- Chukku (Zingiber officinale)
- Citrarathai (Alpinia officinarum)
- Vetrilai (piper betel)
- Omum (Trachyspermum ammi)
- Murunga pattai (Moringa oleifera) - a mixture of 325 ml surasam
- Vembu nei (Azadirachta indica) - 325 ml

Ref: K.S.Murugesa mudhaliyar – Kuzhandhai Maruthuvam (Balavagadam) 5th Edition Indian System of Medicine and Homeopathy Department,Chennai-106 (2010) pg no 93

Ingredients of Chukku nei (Internal)

Fig no.4.1 Zingiber officinalis

Fig no.4.2 Trachyspermum ammi

Fig no. 4.3. Piper betel

Fig no. 4. 4 Alpinia officinarum

Fig no.4.5 –Moringo oleifera

Fig no.4. 6 – Neem oil(Azadirachta indica)

Fig no.4.7 chukku nei

Purification Method:

- Arathai - Remove the outer layer,cut into small pieces and dry it under shadow
- Omum - Soaked in limestone water and dry it
- Murungapattai - Clean and remove the outer layer
- Chukku - Double amount of limestone will be added with an amount of chukku fried for a period of 3 hours after that wash it,remove the outer layer and dry it
- Vembu nei - It will be boiled with equal quantity of neem bark decoction

- **Method of preparing Chukkunei**:

All the ingredients except vembu nei were taken and grind with sufficient quantity of water and make it as surasam (325 ml) then vembu nei (325ml) will be mixed together and boiled and filtered it.

Dosage : 5 ml once a day at morning

Drug Storage:

Prepared medicine in oil form was stored in clean and dry air tight container.

Dispensing:

Prepared medicine of 5 ml oil given in separate dry air tight container.

CHINNI THUVALAI (EXTERNAL)

Ingredients

- Chinni ilai (Acalypha fruticosa)
- Notchi ilai (Vitex negundo)
- Seenthil ilai (Tinospora cordifolia)
- Vembu ilai (Azadirachta indica)

Ref: K.S.Murugesa mudhaliyar Kuzhandhai Maruthuvam (Balavagadam) 5th Edition Indian System of Medicine and Homeopathy Department, Chennai-106 (2010) pg no 68

Ingredients of Chinni thuvalai (External)

Fig no.4.7- Azadirachta indica

Fig no.4. 8 - Vitex negundo

Fig no.4. 9 – Tinospora cordifolia

Fig no.4.10 – Acalypha fruticosa

Preparation

All the leaves were slightly heated and the juices were extracted separately then mixed all together.

Application

The prepared Chinni thuvalai mixture has to be applied over both upper limbs and lower limbs for 3 days as thuvalai.

Indication

All types of Mantham cured

PRECLINICAL STUDIES

4.1. Physicochemical Analysis

The physicochemical analysis of the test drug Chukku nei was carried out as per WHO guidelines **(**Anonymous 1998). The test procedures were done in Noble research solutions, perungudi, Chennai. Since the form of the drug is in oil.

Determination of specific gravity

Fill the dry sp. gravity bottle with prepared samples in such a manner to prevent entrapment of air bubbles after removing the cap of side arm. Insert the stopper, immerse in water bath at 50^{O}C and hold for 30 min. Carefully wipe off any substance that has come out of the capillary opening. Remove the bottle from the bath, clean and dry it thoroughly. Remove the cap of the side and quickly weigh. Calculate the weight difference between the sample and reference standard.

Determination of Weight per ml

Weight per ml was determined using the comparative weight calibration method, in which the weight of 1ml of the base of the formulation was calculated and then weight of 1 ml of finished formulation were been calculated. The difference between weight variations of the base with respect to finished formulation calculated as an index of weight per ml.

Determination of Refractive Index

Determination of RL was carried out using Refractometer.

Determination of Viscosity value

Viscosity determination were been carried out using Ostwald viscometers. Measurement of viscosity involves the determination of the time required for a given volume of liquid to flow through a capillary. The liquid is added to the viscometer, pulled into the upper reservoir by suction, and then allowed to drain by gravity back into the lower reservoir. The time that it takes for the liquid to pass between two etched marks, one above and one bellow the upper reservoir, is measured.

Determination of pH

One gram of the testdrug was taken into a 100ml graduated cylinder containing about 50 ml of water. The cylinder was shaken vigorously for two minutes and the suspension was allowed to settle for hour at 25ºC to 27ºC, then 25 ml of the clear aqueous solution was transfered in to a 50 ml beaker and tested for pH using digital pH meter .

Determination of Iodine value

About 20 gm of test sample was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed by this about 25 ml of Wiji's solution was added in the same flask and shaken well. The flask was allowed to stand for 30 mins and refrigerated for an hour.T About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point. Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

Determination of saponification value

About 2 gm of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeatthe same procedure with out taking the sample for blank titration . Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.

Acid Value

Accurately 5 g of test sample was weighed and transferred into a 250 mL conical flask. To this, a 50 mL of neutralized alcohol solution was added. This mixture was heated for 10 min by heating mantle. Afterwards, the solution was taken out after 10 min and 1 or 2 drops of phenolphthalein indicator was added. This solution was titrated against KOH solution from the burette. The appearance of pink color indicated the end point. The volume of consumed KOH solution was determined and the titration of test sample was carried out in triplicate and the mean of the successive readings was used to calculate the acid-value of the respective sample by following expression.

Acid value = Titter Value X 0.00561X 1000 / Wt of test sample (g)

Peroxide value

5 g of the substance being examined, accurately weighed, into a 250-ml glass-stoppered conical flask, add 30 ml of a mixture of 3 volumes of glacial acetic acid and 2 volumes of chloroform, swirl until dissolved and add 0.5ml volumes of saturated potassium iodide soluton. Allow to stand for exactly 1 minute, with occasional shaking, add 30 ml of water and titrate gradually, with continuous and vigorous shaking, with 0.01M sodium thiosulphate until the yellow colour almost disappears. Add 0.5 ml of starch solution and continue the titration, shaking vigorously until the blue colour just disappears (a ml). Repeat the operation omitting the substance being examined (b ml). The volume of 0.01M sodium thiosulphate in the blank determination must not exceed 0.1 ml.

Calculation : Peroxide value = 10(a-b)/w

TLC Analysis

Test sample was subjected to thinlayer chromatography (TLC) as per conventional one dimensional ascending method using silica gel 60F254, 76 cm (Merck) were cut with ordinary household scissors. Plate markings were made with soft pencil.micro pipette were iused to plot the samplr for TLC applied sample volume 10-microliter by using pipette at adistance of 1 cm at 5 tracks. In the twin trough chamber with different solvent system Toulene : Ethyl Acetate:Acetic Acid (1.5:0.5) after the run plates are dried and was observed using visible light short wave UV light 254 nm and long light wave UV light365 nm.

High Performance Thin Layer Chromatography Analysis (HPTLC)

HPTLC method is a sophisticated and automated selection technique derived from TLC. Pre coated HPTLC graded plates and auto sampler was used to achieve precision,sensitive,significant separation both qualitatively and quantitatively. HPTLC is a valuable quality assessment tool for the evaluation of botanical materials efficiently and cost effectively. It offers high degree of selectivity, sensitivity and rapidity combined with single step sample preparation. In addition it is a reliable method for the quantitation of nano grams level of samples. Thus this method can be conveniently adopted for routine quality control analysis. It provides chromatographic finger prints of phytochemicals which is suitable for confirming the identity purity of medicinal plant raw materials.

Chromatogram development

It was carried out in CAMAG twin trough chambers. Sample elution was carried out according to the adsorption capability of the component to be analysed. After elution, platees were taken out of the chamber and dried.

Scanning

Plates were scanned under UV at 366 nm. The data obtained from scanning were brought into integration through CAMAG software. Chromatographic finger print ewas developed for the detection of phytoconstituentsbpresent in each extract and Rf value were tabulated

Flourescent analysis

Fluorescence analysis in dried powder

Sample CN was subjected to fluorescence analysis under visible light and UV – Light at 365 nm under closed circuit cabinet. Each fluorescence characteristic of the treated sample was observed underordinary light and then under UV light of wave lengths 365 nm. The drug was treated with acids viz., Conc. HCl, Conc. H_2SO_4, Conc. HNO_3 and glacial acetic acid. The drug was treated with alkaline solutions viz., aqueous NaOH and ferric chloride. They were subjected to fluorescence analysis in visible light and in short UV- light (254 nm) and long UV- light (365 nm)

Fig no. 4.1.1 Visible light

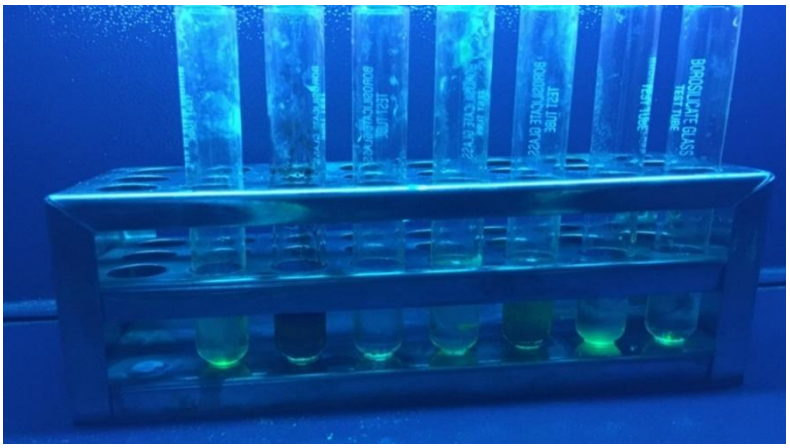
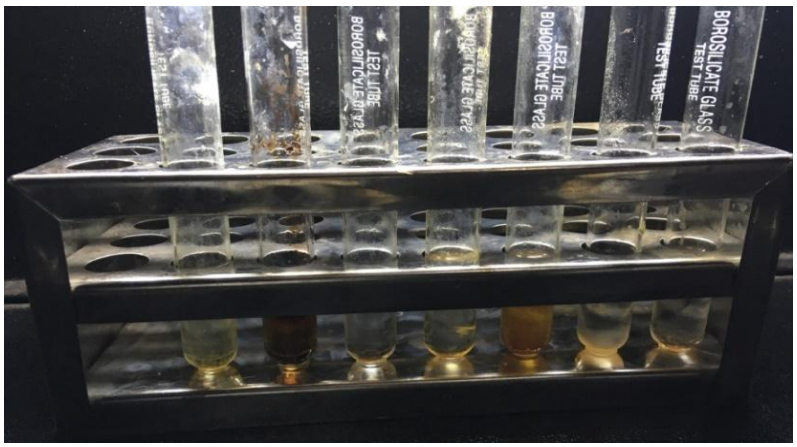


Fig no.4.1.2 Short UV light – 254 nm

Fig no. 4.1.3 Long UV light– 365 nm



Test for Heavy metal Analysis

Atomic Absorption Spectrometry (AAS) is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test sample **.**Test sample digested with 1mol/L HCl for determination of arsenic and mercury.Similarly for the determination of lead and cadmium the sample were digested with 1mol/L ofHNO3.

Sterlity test by pour plate method

Methodology

About 1ml of the test sample was inoculated in sterile petri dish to which about 15 mL of molten agar 45^{o}C were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (about 10 minutes). Plates were then inverted and incubated at 37^{o} C for 24-48 hours. Grown colonies of organism was then counted and calculated for CFU.

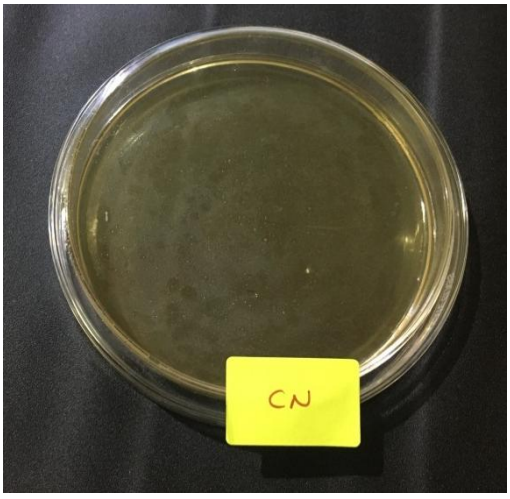


Fig no.4.1.4 Test sample with agar

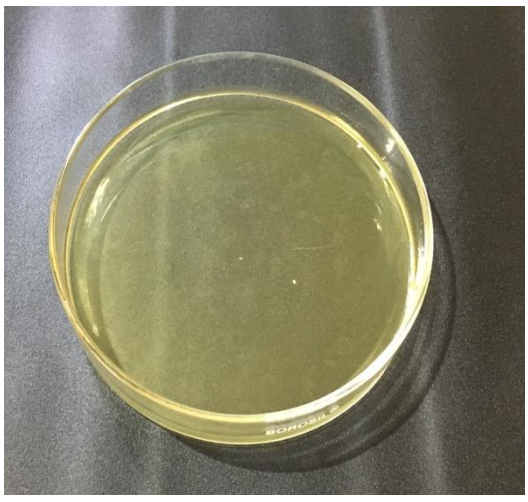


Fig no.4.1.5 No growth colonies

Test for specific pathogen

Methodology

0.5 ml of the test sample was directly inoculated in to the specific pathogen medium (EMB, DCC, Mannitol ,Cetrimide) by pour plate method. The plates were incubated at 37^{o}C for 24

– 72 hr for observation. Presence of specific pathogen identified by their characteristic color with respect to pattern of colony formation in each differential media.

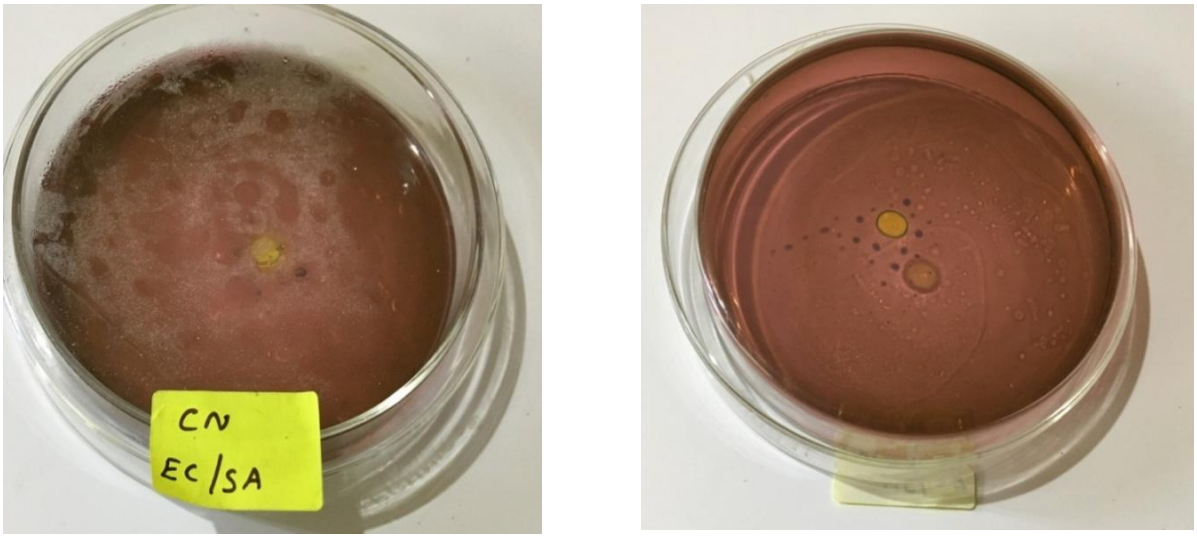


Fig no.4.1.6 Culture plate with e.coli and salmonella specific medium

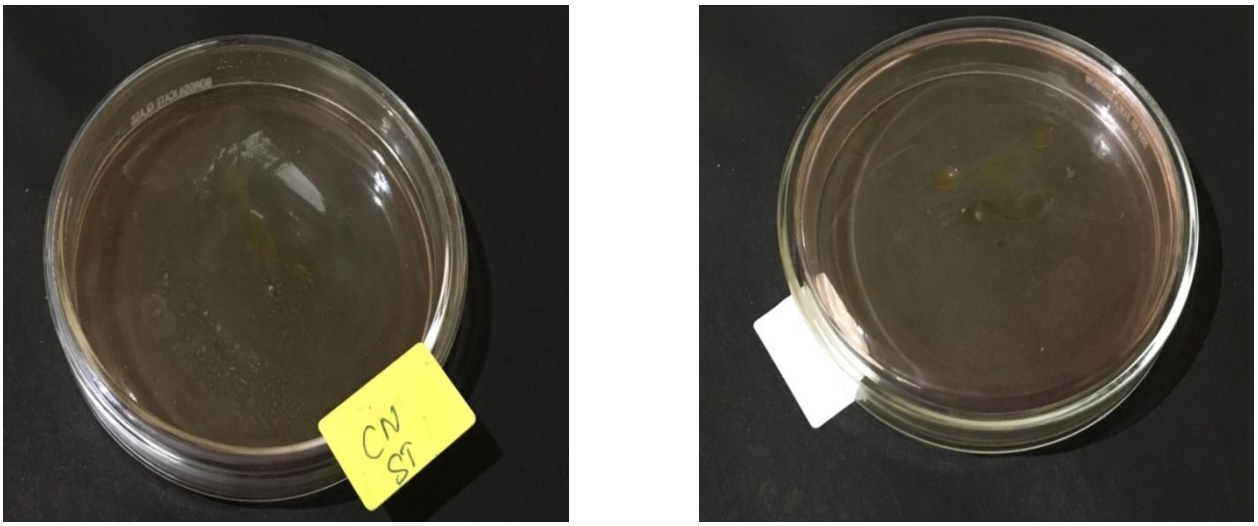


Fig no. 4.1.7 Culture plate with staphylococcus aureus specific medium

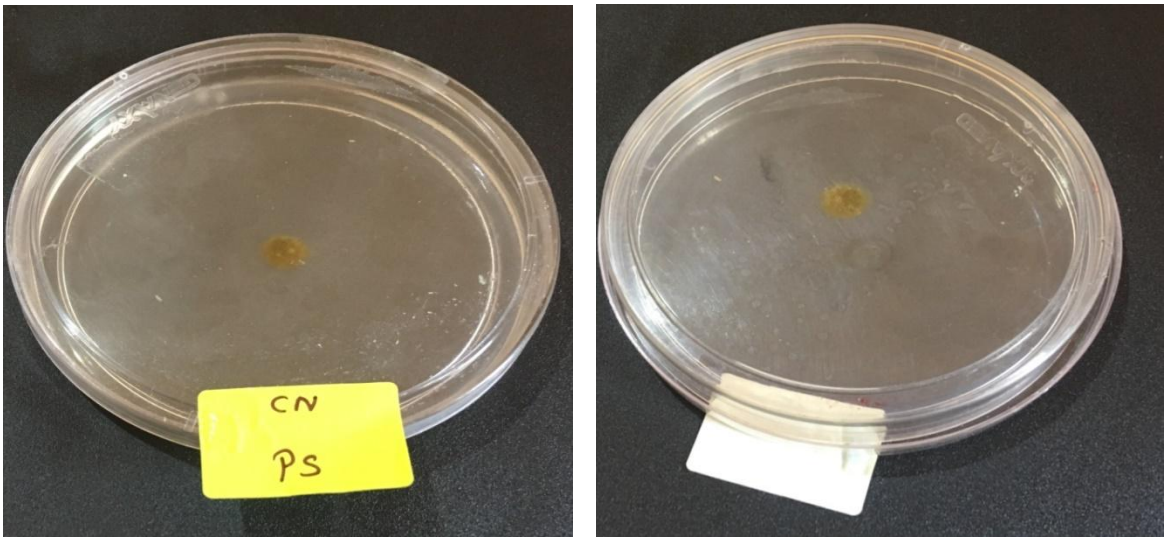


Fig no.4.1.8 Culture plate with pseudomonas aureus specific medium

Test for Organochlorine pesticide, organophosphorous pesticide and pyrethroids

About 10 g of test substance were extracted with 100 ml of acetone and followed byhomogenization for brief period. Further filtration was allowed and subsequent addition of acetone to the test mixture. Heating of test sample was performed using a rotary evaporator at a temperature not exceeding 40ºC until the solvent has almost completely evaporated. To the residue add a few milliliters of toluene R and heat again until the acetone is completely removed. Resultant residue will be dissolved using toluene and filtered through membrane filter.

Aflotoxin Assay by TLC

Standard aflatoxin was applied on to the surface to pre coated TLC plate in the volume of 2.5 µL, 5 µL, 7.5 µL and 10 µL. Similarly the test sample was placed and Allow the spots to dry and develop the chromatogram in an unsaturated chamber containing a solvent system consisting of a mixture of chloroform, acetone and isopropyl alcohol (85 : 10 : 5) until the solvent front has moved not less than 15 cm from the origin. Remove the plate from the developing chamber, mark the solvent from and allow the plate to air-dry. Locate the spots on the plate by examination under UV light at 365 nm.

4.2. Phytochemical Analysis

Sample preparation

Chukku nei (CN) was extracted with ethanol and the extracted was subjected to following analysis

Test for alkaloids:

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

Test for coumarins:

To the test sample, 1 ml of 10% sodium hydroxide was added. The presence of coumarins is indicated by the formation of yellow color.

Test for saponins:

To the test sample, 5 ml of water was added and the tube was shaken vigorously. Copious lather formation indicates the presence of Saponins.

Test for tannins:

To the test sample, ferric chloride was added, formation of a dark blue or greenish black color showed the presence of tannins.

Test for glycosides- Borntrager's Test

Test drug is hydrolysed with concentrated hydrochloric acid for 2 hours on a water bath, filtered and the hydrolysate is subjected to the following tests. To 2 ml of filtered hydrolysate, 3 ml of choloroform is added and shaken, choloroform layer is separated and 10% ammomia solution is added to it. Pink colour indicates presence of glycosides.

Test for flavonoids:

To the test sample about 5 ml of dilute ammonia solution were been added followed by addition of few drops of conc. Sulfuric acid. Appearance of yellow color indicates the presence of Flavonoids.

Test for phenols:

Lead acetate test: To the test sample; 3 ml of 10% lead acetate solution was added. A bulky white precipitate indicated the presence of phenolic compounds.

Test for steroids:

To the test sample , 2ml of chloroform was added with few drops of conc. Sulphuric acid (3ml), and shaken well. The upper layer in the test tube was turns into red and sulphuric acid layer showed yellow with green fluorescence. It showed the presence of steroids.

Triterpenoids

Liebermann–Burchard test: To the chloroform solution, few drops of acetic anhydride was added then mixed well. 1 ml concentrated sulphuric acid was added from the sides of the test tube, appearance of red ring indicates the presence of triterpenoids.

Test for Cyanins

A. Aanthocyanin:

To the test sample, 1 ml of 2N sodium hydroxide was added and heated for 5 min at 100□C. Formation of bluish green colour indicates the presence of anthocyanin.

Test for Carbohydrates - Benedict's test

To the test sample about 0.5 ml of Benedic's reagent is added. The mixture is heated on a boiling water bath for 2 minutes. A characteristic coloured precipitate indicates the presence of sugar.

Proteins (Biuret Test)

To extracts 1% solution of copper sulphate was added followed by 5% solution of sodium hydroxide, formation of violet purple colour indicates the presence of proteins.

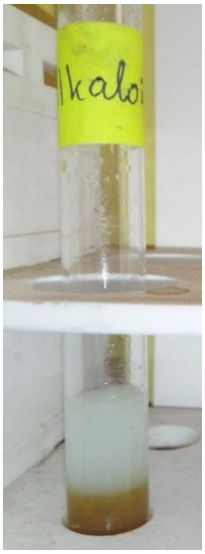


Fig no.4.2.1Test for Alakaloid

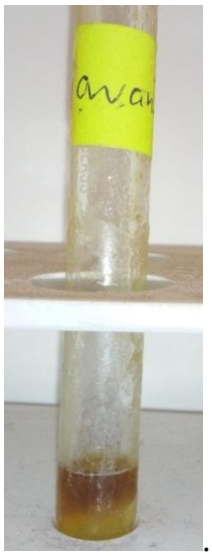


Fig no.4.2.2Test for Flavanoid

Fig no.4.2.3Test for Glycosides

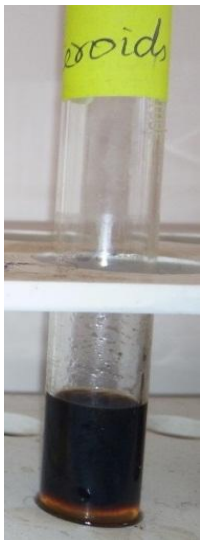


Fig no.4.2.4Test for Steroids

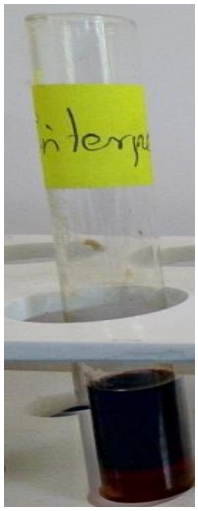


Fig no.4.2.5 Test for Coumarin

Fig no.4.2.6Test for Triterpenoids

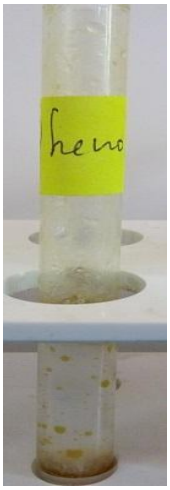


Fig no.4.2.7Test for Phenols

Fig no.4.2.7 Test for Tannin

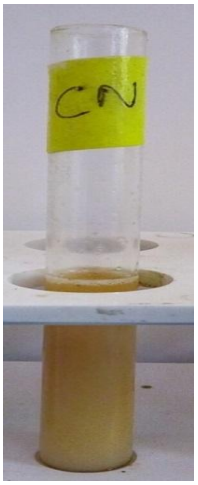


Fig no.4.2.8Test for protein

Fig no.4.2.9Test for Saponin

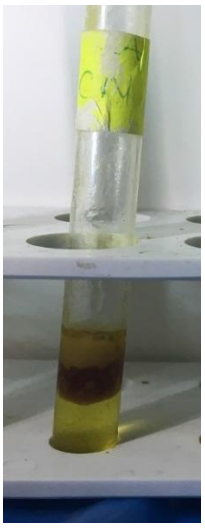


Fig no. 4.2.10 Test for Carbohydrate

Fig no.4.2.11Test for Beta cyanin

4.3. Biochemical Analysis

Biochemical Analysis of Chukku nei was done at the Biochemistry lab at National Institute of Siddha, Chennai by the method of Kolkate.

Preparation of Extract:

5ml of sample was taken in a 250ml clean beaker and added with 50ml of distilled water. Then it is boiled well for about 10 minutes. Then it is cooled and filtered in a 100ml volumetric flask and made up to 100ml with distilled water. This preparation is used for the qualitative analysis of acidic/basic radicals and biochemical constituents in it.

Procedure:

Test for Silicate

A 2ml of the sample was shaken well with distilled water.

Action of Heat:

A 2ml of the sample was taken in a dry test tube and heated gently at first and then strong.

Ash Test:

A filter paper was soaked into a mixture of extract and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited

4.3.1. Test for Acid Radicals

Test for Sulphate:

2ml of the above prepared extract was taken in a test tube to this added 2ml of 4% dil ammonium oxalate solution

Test for chloride:

2ml of the above prepared extracts was added with 2ml of dil.HCl is added until the effervescence ceases off.

Test for Phosphate:

2ml of the extract were treated with 2ml of dil.ammonium molybdate solution and 2ml of con.HNo3.

Test for carbonate:

2ml of the extract was treated with 2ml of dil. magnesium sulphate solution.

Test for Nitrate:

1gm of the extract was heated with copper turning and concentrated H_2So_4 and viewed the test tube vertically down.

4.3.2. Test for Basic radicals

Test for lead:

2ml of the extract was added with 2ml of dil.potassium iodine solution.

Test for copper:

One pinch (25mg) of extract was made into paste with con. HClin a watch glass and introduced into the non-luminuous part of the flame.

Test for Aluminium:

To the 2ml of extract dil.sodium hydroxide was added in 5 drops to excess.

Test for Iron:

a. To the 2ml of extract add 2ml of dil.ammonium solution

b. To the 2ml of extract 2ml of thiocyanate solution and 2ml of con HNo3 is added.

Test for Zinc:

To 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess and dil. ammonium chloride were added.

Test for Calcium:

To 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution

Test for Magnesium:

To 2ml of extract dil.sodium hydroxide solution was added in drops to excess.

Test for Ammonium:

To 2ml of extract 1 ml of Nessler's reagent and excess of dil.sodium hydroxide solution are added.

Test for Potassium:

A pinch (25mg) of extract was treated of with 2ml of dil.sodium nitrite solution and then treated with 2ml of dil.cobalt nitrate in 30% dil.glacial acetic acid.

Test for Sodium:

2 pinches (50mg) of the extract is made into paste by using HCl and introduced into the blue flame of Bunsen burner.

Test for Mercury:

2ml of the extract was treated with 2ml of dil.sodium hydroxide solution.

Test for Arsenic:

2ml of the extract was treated with 2ml of dil.sodium hydroxide solution

4.3.3 Miscellaneous

Test for Starch:

2ml of extract was treated with weak dil.Iodine solution**.**

Test For Reducing Sugar:

5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes. The colour changes are noted.

Test for alkaloids:

Mayer's Test: To the test sample, 2ml of mayer's reagent was added, a dull white precipitate revealed the presence of alkaloids.

Test for tannic acid:

To the 2 ml of extract was treated with 2 ml of dil.ferric chloride solution

Test for Unsaturated Compound:

To the 2ml of extract 2ml of dil.Potassium permanganate solution was added**.**

Test for AminoAcid:

2 drops of the extract was placed on a filter paper and dried well. 20ml of Burette reagent is added**.**

Test for Type of Compound:

2ml of the extract was treated with 2 ml of dil.ferric chloride solution.

4.4. Pharmacological Activity

In-vitro Carminative Activity

Project ID	:	NRS/AS/0087/01/2018
Institute	:	National Institute of Siddha
Sample Name	:	Chukku nei
Sample ID	:	CN

In-vitro Carminative activity acid-base titration Method

In-vitro carminative activity of the chukka Nei was evaluated by modified method of Swapnil Sharma et al. About 10,20 and 40 ml of the CN were placed in conical flask fitted with air-tight nozzle, to this 100 ml of distill water was added. About 100 ml of NaOH {1M, previously standardized to oxalic acid} was poured into a plastic container fitted with aeration tubing system that was connected directly to the reaction vessel containing varying volume of CN. The flask was agitated manually for the next 45 mins and vigorously for another 30 mins and was allowed to stand for overnight. The carbon dioxide gas evolved from the reaction vessel was allowed to pass into a plastic container containing excess sodium hydroxide where it was absorbed and converted into equivalent amount of sodium carbonate. The resulting mixture consisting of excess sodium hydroxide and sodium carbonate was titrated with standard HCl using phenolphthalein as indicator to get first endpoint and in continuation to this the second endpoint was enumerated using methyl orange as indicator. The difference in milliliters between the first & second endpoints was used to calculate the carbon dioxide content per gram of sample.

Vol. of titrant x molarity of std. acid x mol. Wt. of CO_2 = mass of CO_2 in gm

Molarity of the Acid is 0.09184 M

Mol. Wt. of CO_2 is 44.01 g/mol

Triplicate 1

Volume of Test Sample	Difference in Titration value (ml)	Mass of CO2 in gm
10	1.7	6.87
20	2.4	9.70
40	4.8	19.40

Triplicate 2

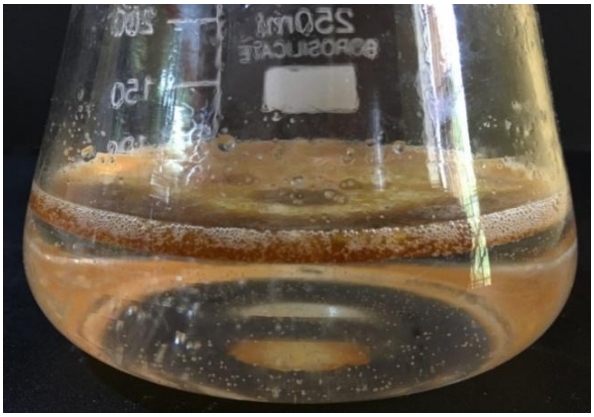
Volume of Test Sample	Difference in Titration value (ml)	Mass of CO2 in gm
10	1.4	5.65
20	2.3	9.29
40	5.0	20.20

Triplicate 3

Volume of Test Sample	Difference in Titration value (ml)	Mass of CO2 in gm
10	2.0	8.08
20	2.8	11.31
40	4.4	17.78

Fig no. 4.4.1 Reaction setup
Sample Chukku nei

Fig no. 4.4.2Evolvement of
carbon dioxide from the reaction mixture



4.5. Clinical Studies

Population and Sample:

The population consists of paediatric patients attending the OPD of AyothidossPandithar Hospital, National Institute of Siddha, Chennai - 47. The sample consists of 1-3 years age group fulfilling any four of the inclusion criteria and none of the exclusion criteria.

Sample size : 30 Patients

Study place **:** OPD &IPD of Ayothidosspandithar Hospital,
National Institute of Siddha, Tambaram sanatorium, Chennai – 47.

Inclusion criteria:

Age 1 to 3 years

Sex: Both male and female children.

Children with minimum four clinical symptoms such as

[

1. Constipation
2. Poor appetite
3. Borborygmus/stomach pain
4. Cough
5. Fever
6. Yawning

Exclusion criteria

1. High temp > 102 F

2. Intolerable stomach pain

3. Constipation more than 1 week

4. Patient not willing to give biological samples whenever needed

Withdrawl criteria:

1. Occurrence of any adverse effect
2. Poor patient compliance &defaulters.
3. Patient turned unwilling to continue in the course of clinical trial.
4. Exacerbation of symptoms

Study design : An Open clinical trial.

Study duration : 12 Months

Name of the trial drug : Chukkunei (internal) and Chinni thuvalai (external)

Dosage of drugs : 5ml(od) at morning

Chinni thuvalai for 3 days at morning

A.Clinical Assessment

Clinical assessment were done with reduction of following clinical symptoms and also using Bristol Stool Chart.

- Constipation
- Poor appetite
- Borborygmus/Stomach pain
- Fever
- Cough
- Yawning

B.Siddha Method of Assessment

Clinical aasessment also done using the following variables according to Siddha Methodology

- Nilam
- Kaalam
- Uyirthathukkal
- Udalthaathukkal
- Envagaithervugal

Study Enrollment:

1. In this study, patients reporting at the NIS OPD with the four or more clinical symptoms were examined clinically for enrolling in this study based on the inclusion and exclusion criteria.
2. The patients who were to be enrolled in this study were informed (Form VI) about the study, experimental medicine, possible outcomes and the objectives of the study in the language and terms understandable to them and to their informants.

3. After ascertaining the patient and informant willingness, informed consent was obtained in writing from them in the consent form (Form II).

4. All these patients were given unique registration card in which patients' Registration number of the study, Address, Phone number and Doctors phonenumber etc. will be given, so as to report easily communication for the sake of the patient.

5. Complete clinical history, complaints and duration, examination findings - all were be recorded in the prescribed Proforma in the history and clinical assessment forms (form IV) separately. Screening Form- I will be filled up; Form III was be used for recording the patients' history, clinical examination of symptoms and signs respectively.

6. Patient were advised to take the trial drug and appropriate dietary advice (Form X) was given according to the patients' perfect understanding.

Conduct of the Study:

The trial drug "Chukku nei"(Internal) and "Chinni thuvalai" (External) were given for 3 days. For OP patients the clinical assessment was done and prognosis noted on 0^{th}day and 4^{th} day. For IP patients the drug was provided and prognosis noted and clinical assessment was done on 1^{st} day itself.

The patients were treated with trial drugs Chinni thuvali (external therapy) at morning, after finishing the therapy patients were adviced to take bath with warm water. Then the trial drug Chukku nei was given orally with a dosage of 5 ml. OPD patients were instructed to come regularly for 3 days and advised to follow the diet.

Data Managment:

After enrolling the patient in this study, a separate file for each patient was opened and all forms were filed in the file. When the patient visits OPD during the study period, the respective patient file was taken and necessary recordings made at the assessment form or other suitable form.The screening forms werefiled separately.

The Data recordings were monitored for completion and any adverse event by HOD and data logical recording and completeness monitored by statistician (Sr.Research Officer (Statistics) .All forms were further scrutinized in presence of Investigator by Sr.Research

Officer (SRO) for logical errors and incompleteness of data before entering onto computer to avoid any bias. No modification in the results is permitted for unbiased report.

If any missed data found during the study, it was collected from the patient, but the time related data not be recorded retrospectively. All the collected data were enteredonto computer using MS access software.Investigator was trained to enter the patient data and cross checked by SRO.

Advese Effect/Serious Effect Management:

If the trial patient develops any adverse reaction, he/she would be immediately withdrawn from the trial and proper management will be given in OPD of National institute of siddha and the same will be reported to regional pharmacovigilance center.

Ehical Issues:

1. No other external or internal medicines were used.
2. The data collected from the patient's informant was recorded. The patient's informant was informed about the diagnosis, treatment and follow-up.
3. After the consent of the patient's informant (through consent form), patient was enrolled in the study
4. Informed consent was obtained from the patient's informant explaining in the understandable language to the patient's informant.
5. Treatment was provided free of cost.
6. In conditions of treatment faliure, adverse reactions, patients will be given alternative treatment at the National Institute of Siddha with full care.

Data Collection Forms:-

Form I	Screening & Selection Proforma
Form II	Consent Form
Form III	Case report form
Form IV	AssessmentForm
Form V	Patient Information Sheet
Form VI	Drug compliance
Form VII	Withdrawal
Form VIII	Adverse reaction
Form IX	Pharmaco vigilance
Form X	Dietary form

CHAPTER V

5. RESULTS AND OBSERVATIONS

Preclinical studies:

5.1. Physicochemical analysis of chukku nei

Table No.5.1.1Final test report

State	Liquid
Appearance	Reddish Brown
Nature	Viscous Liquid
Odor	Strong Characteristic

Table No. 5.1.2

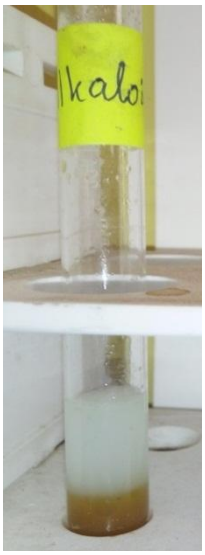
S.No.	Specific Test	Results
1	Specific gravity	0.9471
2	Viscosity at 50c (pa s)	33.019
3	Refractive index	1.46
4	Weight per ml (gm/ml)	0.068 gm/ml
5	Iodine value (mg I2/g)	172.08
6	Saponification value (mh of KOH to sdaponify 1gm of fat)	262.43
7	PH	4
8	Acid value mg KOH/g	3.104
9	Peroxidase value mEq/kg	2.325

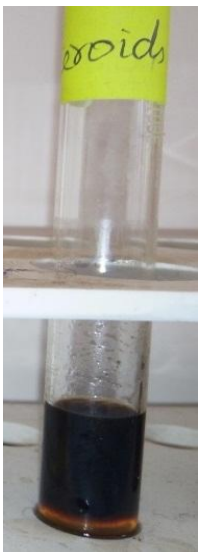
5.2. Phytochemical analysis of chukku nei

Table no. 5.2.1

S.NO	TEST	OBSERVATION
1	ALKALOIDS	+
2	FLAVANOIDS	+
3	GLYCOSIDES	-
4	STEROIDS	+
5	TRITERPENOIDS	+
6	COUMARIN	-
7	PHENOL	-
8	TANIN	-
9	PROTEIN	-
10	SAPONINS	+
11	SUGAR	-
12	ANTHOCYANIN	-
13	BETACYANIN	+

5.2.2 Result of Phytochemical Analysis





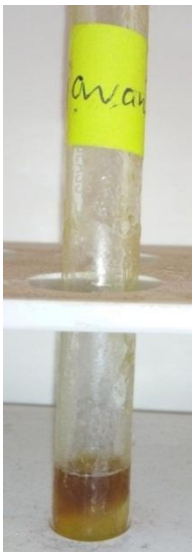
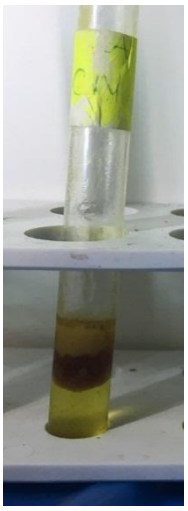
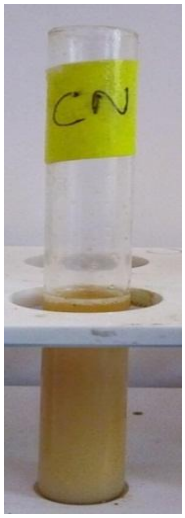


Fig no.1Test for Alkaloid **Fig no.2 Test for Steroid** **Fig no.3 Test for Flavanoid**





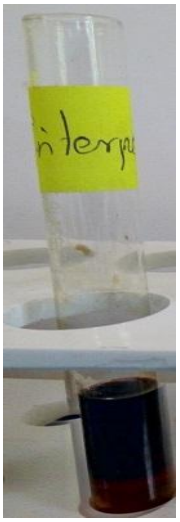


Fig no.4 **Fig no.5** **Fig no. 6**

Test for Beta cyanin **Test for Saponin** **Test for Triterpenoids**

5.3. Biochemical Analysis of chukku nei

Table no.5.3.1 Results of Acid radicals studies

S.NO	Parameter	Observation	Result
1	Test for Sulphate	Cloudy appearance Present	Positive
2	Test for Chloride	-	Negative
3	Test For Phosphate	-	Negative
4	Test For Carbonate	Cloudy appearance present	positive
5	Test For Nitrate	-	Negative
6	Test for Sulphide	-	Negative
7	Test For Fluoride &oxalate	-	Negative
8	Test For Nitrite	-	Negative
9	Test For Borax	-	Negative

Interpretation

The acidic radicals test shows the presence of **Sulphate, Carbonate.**

Table no.5.3.2 Results of basic radicals studies:

S.NO	Parameter	Observation	Result
1	Test for Lead	-	Negative
2	Test for Copper	-	Negative
3	Test For Aluminium.	-	Negative
4	Test For Iron.	Mild red colour	positive
5	Test For Zinc	-	Negative
6	Test for Calcium	Cloudy appearance and white precipitate present	Positive
7	Test For Magnesium	White precipitate obtained	Positive
8	Test For Ammonium	-	Negative
9	Test For Potassium	-	Negative
10	Test For Sodium	-	Negative
11	Test For Mercury	-	Negative
12	Test For Arsenic	-	Negative

Interpretation

The basic radical test shows the presence of **calcium, Magnesium, Carbonate, Iron** and absence of heavy metals such as lead, arsenic and mercury.

Table No.5.3.3 Miscellaneous:

S.NO	Parameter	Observation	Result
1	Test for Starch	-	Negative
2	Test for Reducing sugars	-	Negative
3	Test For Alkaloids.	Yellow colour developed	Positive
4	Test For Tannic acid.	-	Negative
5	Test for unsaturated compounds	-	Negative
6	Test for Amino acid	-	Negative
7	Test For Type of compounds	-	Negative

Interpretation

The Miscellaneous test shows the presence of **Alkaloids**

5.4. Fluorescence Analysis

Table no.5.4.1 fluorescence analysis

S.No	Experiment	Visible light	Short UV – Light 254 nm	Long UV – Light 365 nm
1	Sample + Conc. Hcl	Yellow	Yellow	Fluorescent Yellow
2	Sample + Conc. Sulphuric Acid	Greenish brown	Dark reddish brown	Brown
3	Sample + Conc. Nitric acid	Creamy white	Creamy yellow	Fluorescent yellow
4	Sample + Sodium hydroxide in water	Whitish yellow	Fluorescent yellow	Fluorescent yellow
5	Sample + Ferric chloride	Brownish orange	Fluorescent green	Orange
6	Sample + glacial acetic acid	Creamy white	Lime Yellow	Yellow

Fig no.5.4.2 Thin Layer Chromatography (TLC)

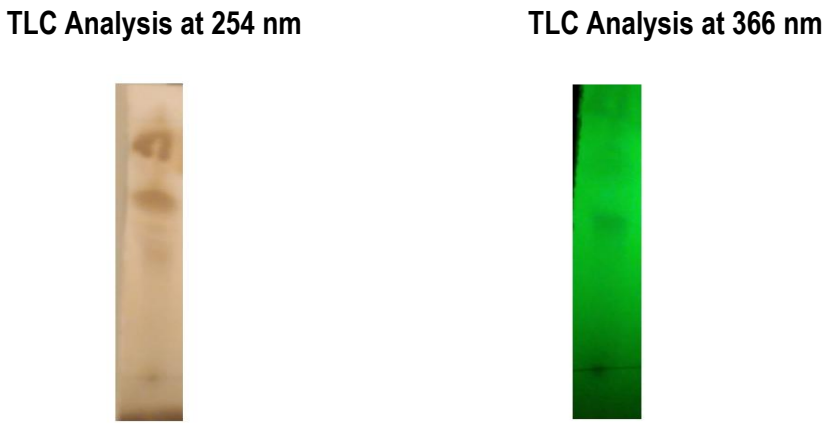


Fig no. 5.4.3 High Power Thin Layer Chromtography (HPTLC)

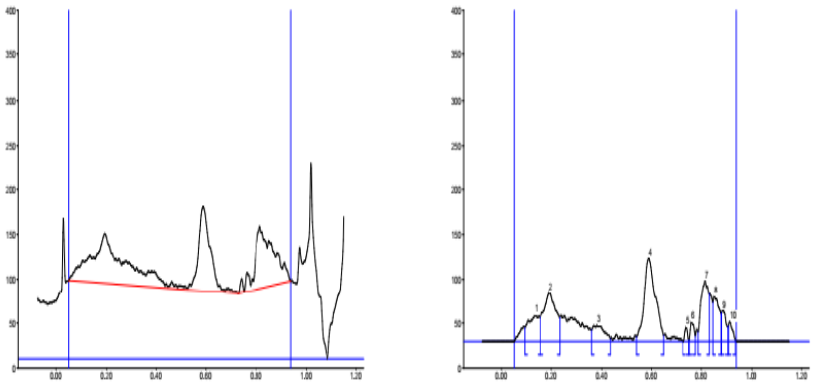


Table no. 5.4.4 HPTLC finger print

HPTLC finger printing analysis of the sample Chukku nei reveals the presence of ten prominent peaks corresponds to presence of ten versatile phytocomponents present with in it. Rf value of the peaks ranges from 0.09 to 0.91. Further the peak 4 occupies the major percentage of area of 30.12 % which denotes the abundant existence of such compound. Followed by this peak 2 and 7 occupies the percentage area of 19.64 and 14.61%.

5.5. Heavy metal analysis of chukku nei

Table no.5.5.1

NAME OF THE HEAVY METAL	ABSORPTION MAX	RESULT ANALYSIS	MAXIMUM LIMIT
MERCURY	253.7 nm	BDL	1 PPM
LEAD	217.0 nm	0.010PPM	10 PPM
ARSENIC	193.7 nm	BDL	3 PPM
CADMIUM	228.8 nm	0.005 PPM	0.3 PPM

Results of the present investigation has clearly shows that Chukku nei has no traces of Mercury and Arsenic. The level of lead and cadmium was found to be 0.010 ppm and 0.005 ppm.Reported heavy metals (lead and cadmium) seems very low when compare to the allowed recommended limit.

Peak	Start Rf	Start Height	Max Rf	Max Height	Max %	End Rf	End Height	Area	Area %
1	0.09	15.6	0.13	29.8	7.21	0.16	26.4	1030.9	9.86
2	0.16	27.4	0.19	55.2	13.36	0.24	26.6	2053.7	19.64
3	0.36	12.8	0.38	18.1	4.38	0.44	2.9	649.1	6.21
4	0.54	5.3	0.59	94.2	22.80	0.65	6.8	3150.1	30.12
5	0.73	0.3	0.74	16.4	3.97	0.75	1.4	126.6	1.21
6	0.75	2.0	0.76	21.8	5.27	0.78	6.3	239.9	2.29
7	0.79	10.5	0.82	69.5	16.83	0.83	53.2	1527.7	14.61
8	0.85	43.4	0.85	50.8	12.29	0.88	31.1	935.9	8.95
9	0.88	31.5	0.89	35.2	8.52	0.91	16.2	487.2	4.66
10	0.91	17.2	0.92	22.1	5.36	0.94	1.9	257.6	2.46

5.6 Sterlity Test by pour plate method

Table no.5.6.1

Test	Result	Specification	As per AYUSH/WHO
Total Bacterial Count	Absent	NMT 10^5CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10^3CFU/g	

No growth / colonies were observed in any of the plates inoculates with the test sample.

5.7. Test for specific pathogen

Table no.5.7.1

Organism	Specification	Result	Method
E-coli	Absent	Absent	As per AYUSH specification
Salmonella	Absent	Absent	
Staphylococcus Aureus	Absent	Absent	
Pseudomonas Aeruginosa	Absent	Absent	

No growth was observed after incubation period. Reveals the absence of specific pathogen.

5.8. Analysis of organochlorine pesticide, organophosphorus pesticide and pyrethroid

The results showed that there were no traces of pesticides residues such as Organo chlorine and Organo phosphorus Pesticides in the sample CN. Further sample shows the presence of Cypermethrin belongs to pyrethroid type of pesticide at the concentration of 0.1 mg/kg which was low when compare the AYUSH prescribed limit of 1mg/kg.

5.9. Test for Aflotoxin

The results shown that there was no spots were been identified in the test sample loaded TLC plated when compare to the standard indicates that he sample were free from Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2.

5.10. Pharmacological Activity : In-vitro carminative Activity

Result Analysis

The carminative profiling of the test sample Chukku nei was evaluated on basis of the amount of cabondioxide evolved from the reaction mixture with varying volume of CN. The amount of cabondioxide {g} produced by the 5ml of the sample CN was found to be for 10 ml of sample it was (6.87 ± 1.21), 20 ml of sample it was (10.1 ± 1.06) and 40 ml of sample it was (19.13 ± 1.23). Each value represents the mean ± SD. N=3. It was concluded that the drug possesses promising carminative activity in the tested medium which was measured as an index of mass of CO_2 released from the medium.

Table no.5.10.1

Volume of Test Sample	Mass of CO2 in gm
0	(6.87 ± 1.21)
20	(10.1 ± 1.06)
40	(19.13 ± 1.23)

Clinical Studies

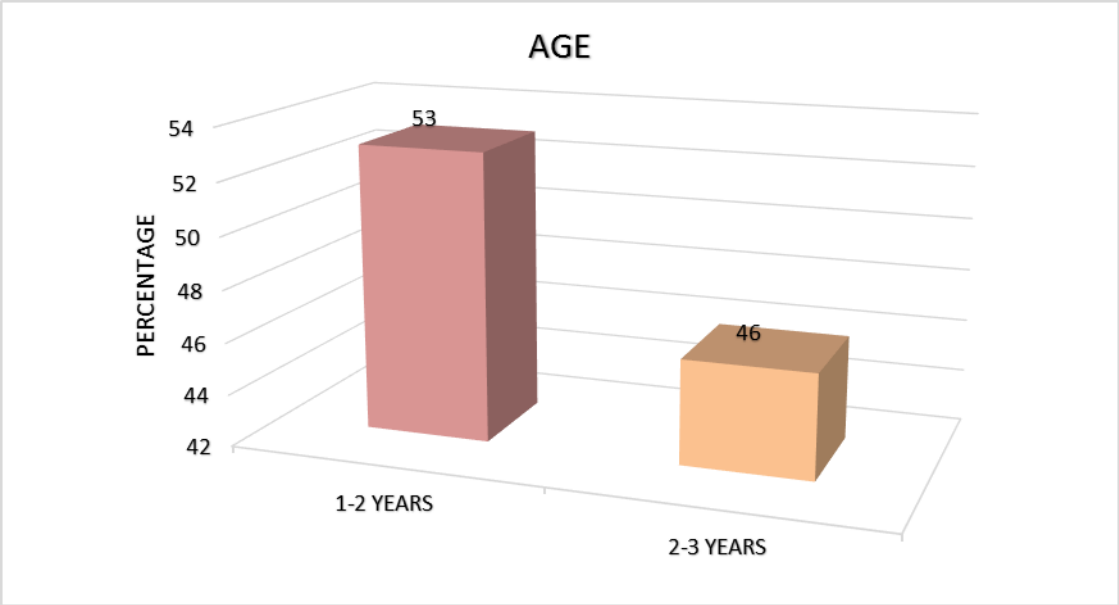
30 Patients with confirmed diagnosis of with satisfying the inclusion criteria were enrolled after obtaining written informed consent and were to receive *Chukku nei* with dosage of 5 mlod for 3 daysand chinni thuvalai as external therapy.

Results were observed with respect to the following criteria:

1. Age
2. Sex
3. Religion
4. Parent's Socio Economic Status
5. Diet
6. Nilam
7. Paruvakaalam
8. Uyirthathukkal
9. Ezhuudalkattugal
10. Envagaithervugal
11. Naadi
12. Neikuri
13. Clinical features

Table1. Distributions of patients with *Kattu Mantham* according to Age

S.NO	AGE	NO.OF.CASES	PERCENTAGE%
1.	1-2 Years	16	53%
2.	2-3Years	14	46%

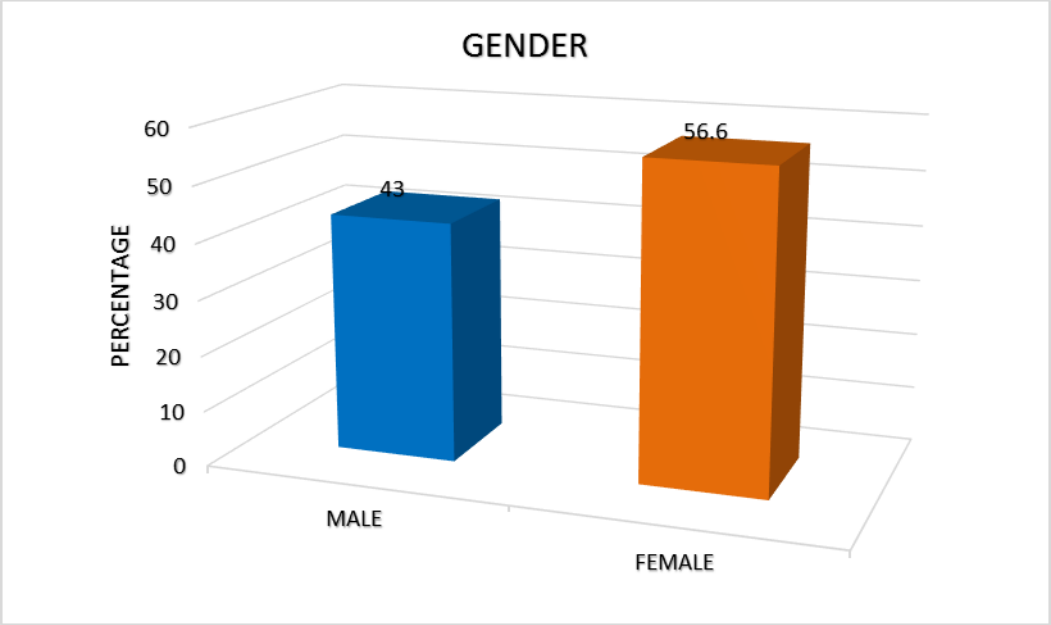


Inference:

Out of 30 patients, 53 % of cases were within 1-2years, 46 %of cases were within 2-3 years. (Table1)

Table2.Distributions of patients with *Kattu mantham* according to Gender

S.No	Sex	No of Cases	Percentage%
1.	Male Child	13	43%
2.	Female Child	17	56.6%

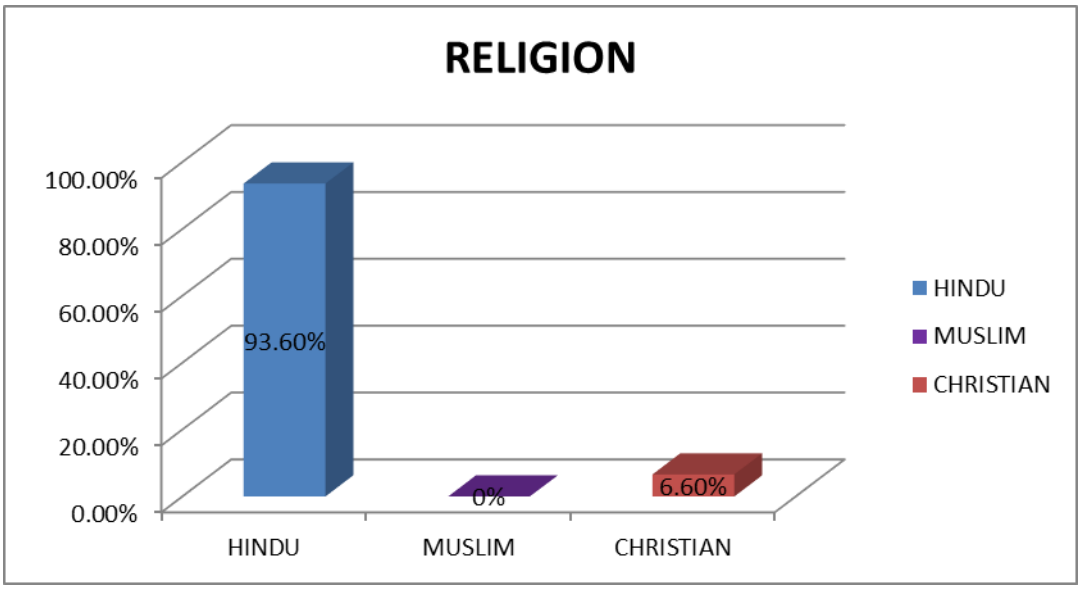


Inference:

Out of 30 patients 43% were male children and 56.6% were female children. (Table 2)

Table.3. Distribution of patients with *Kattu mantham* according to Religion status

Religion	No of Cases	Percentage
Hindu	28	93.3%
Christian	2	6.6%
Muslim	0	0

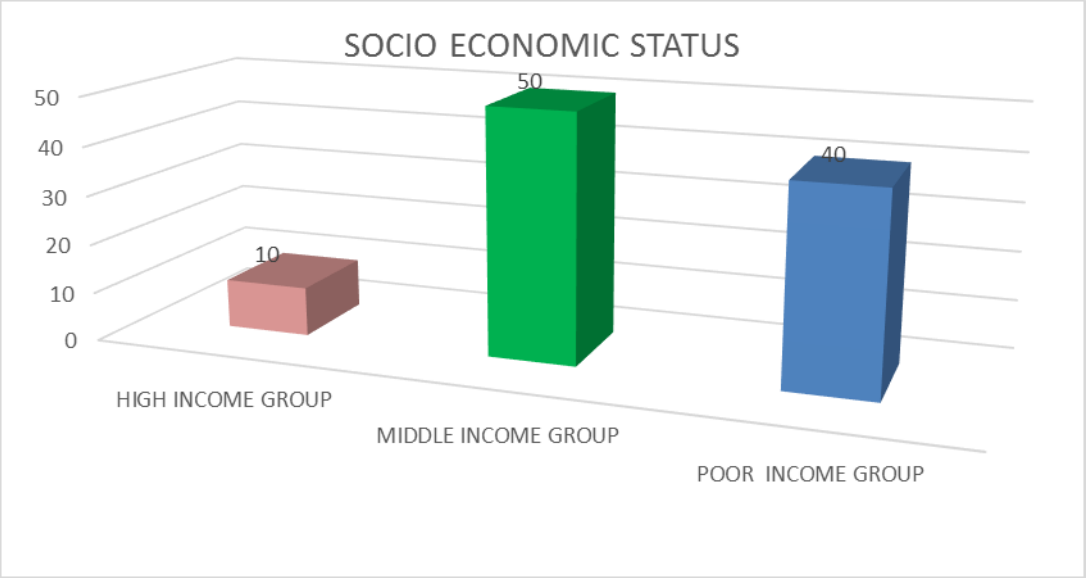


Inference (Religion):

According to Religion, Hindu was reported in 93.3% of cases, Christian was reported in 6.6% of cases and No cases were reported from Muslim community (Table3).

Table 4. Distribution of patients with Kattu mantham according to Socio economic status

S.No	Socio-economic Status	No of Cases	Percentage%
1.	High Income group	3	10
2.	Middle Income group	15	50
3.	Poor Income group	12	40

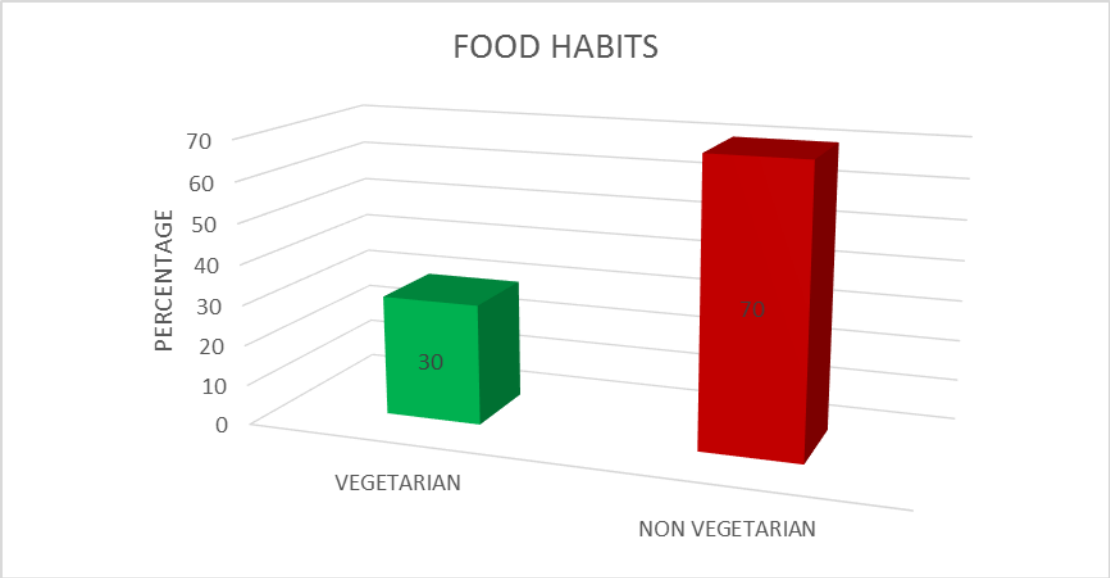


Inference:

About 40% patients were under lower income group, 50% patients were under middle income group and 10% patients were under high income group. The highest incidence occurred in middle income group.(Table 4).

Table 5.Distribution of patients with *Kattu mantham* according to Diet reference

S.NO	FOOD HABITS	NO OF CASES	PERCENTAGE%
1.	Vegeterian	9	30%
2.	Non-Vegeterian	21	70%

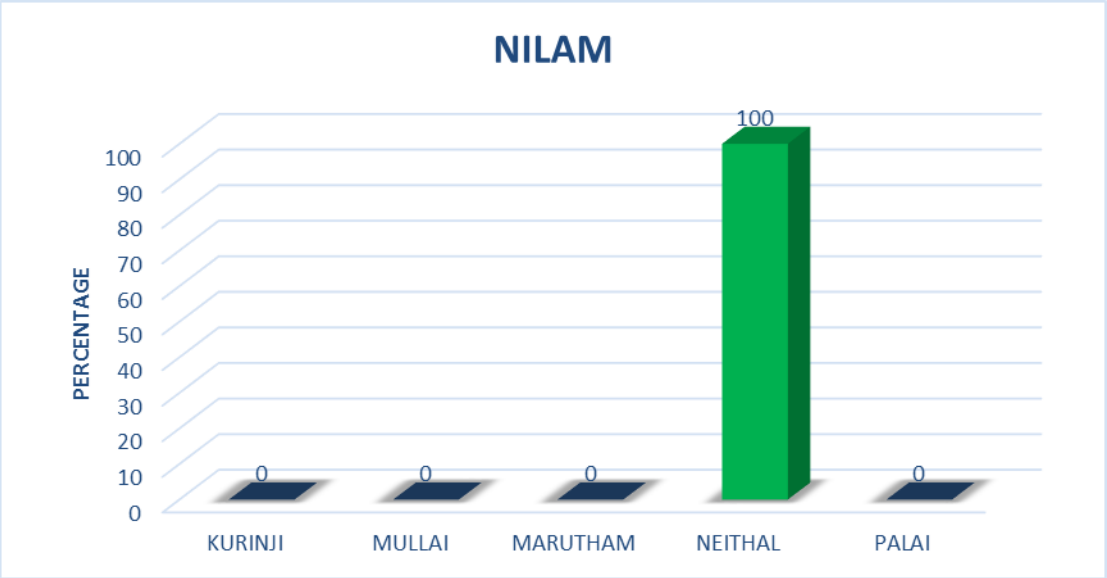


Inference:

According to diet habit, 30% of children are taking Vegetarian food and 70% of them from Non Vegetarian group (Table 5)

Table.6. Distribution of patients with *Kattu mantham* according to Nilam

Nilam	No of cases	Percentage%
Kurinji	0	0
Mullai	0	0
Marutham	0	0
Neithal	30	100%
Paalai	0	0

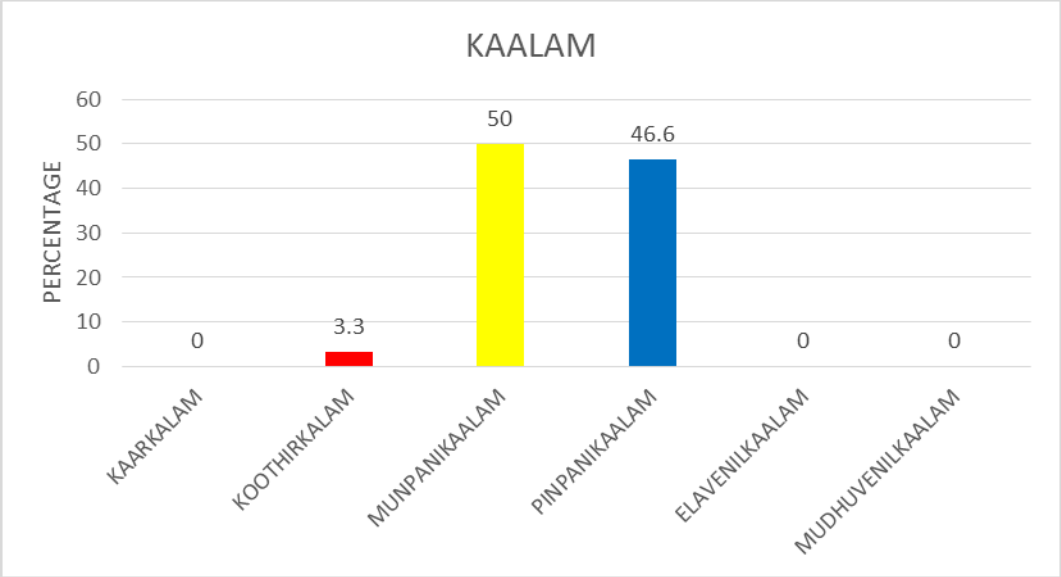


Inference:

Among 30 patients, 100 % were from Neithal land, 0% from Marutham land, 0 % from Mullai land and 0% from Kurinji land.(Table 6)

Table.7. Distribution of patients with *Kattu mantham* according to Paruvakalam

S.No	Paruvakaalam	No. of cases	Percentage
1.	Karkaalam (Avani – puratasi)	0	0
2.	Koothirkaalam (Iyppasi – karthikai)	1	3.3%
3.	Munpani (Markazhi – Thai)	15	50%
4.	Pin pani (Masi – Panguni)	14	46.6%
5.	Elavenil (Chitirai, Vaigasi)	0	0
6.	Mudhuvenil (Aani, Aadi)	0	0

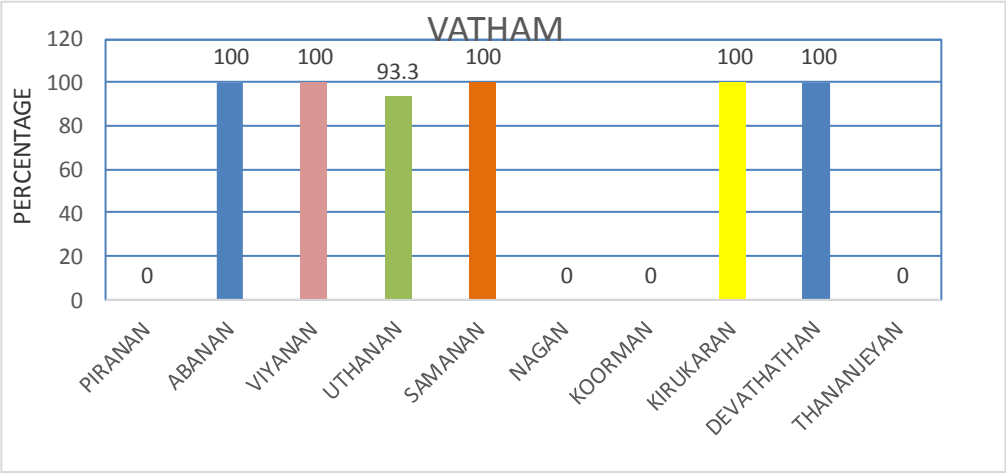


Inference:

According to paruva kaalam, high incidence of cases 50% were reported in munpanikalam, 46.6% cases were reported in pinpani kalam and 1% in koothirkalam .(Table 7)

Table 8.a. Distribution of patients with *Kattu mantham* according to derangement of Vatham

Sl.No.	Type of Vatham	No. Of Cases	Percentage
1.	Piranan	0	0
2.	Abanan	30	100%
3.	Viyanan	30	100%
4.	Uthanan	28	93.3%
5.	Samanan	30	100%
6.	Nagan	0	0
7.	Koorman	0	0
8.	Kirukaran	30	100%
9.	Devathathan	30	100%
10.	Thananjeyan	0	0

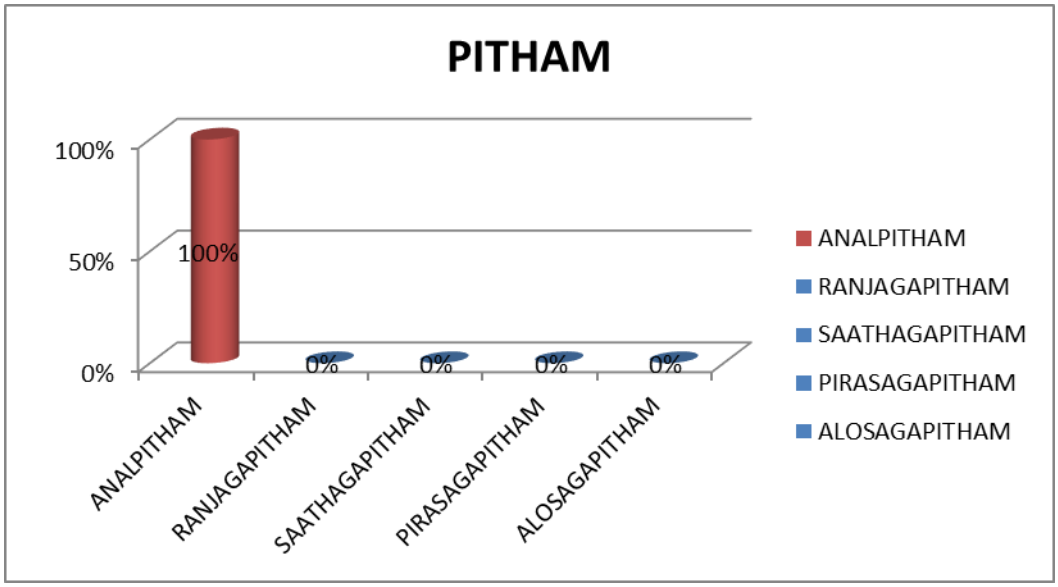


Inference:

According to vatham, Abanan, viyanan, samanan, kirukaran and devathathan were affected in 100% of cases and Udhanan was affected in 93.3% of cases. The remaining piranan, nagan, koorman were not affected in any of the cases. (Table 8a).

Table 8.b. Distribution of patients with *Kattu mantham* according to derangement of Pitham

S.No	Types of pitham	No.of Cases	Percentage
1.	Analapitham	30	100%
2.	Ranjagam	0	0
3.	Saathagam	0	0
4.	Prasagam	0	0
5.	Alosagam	0	0

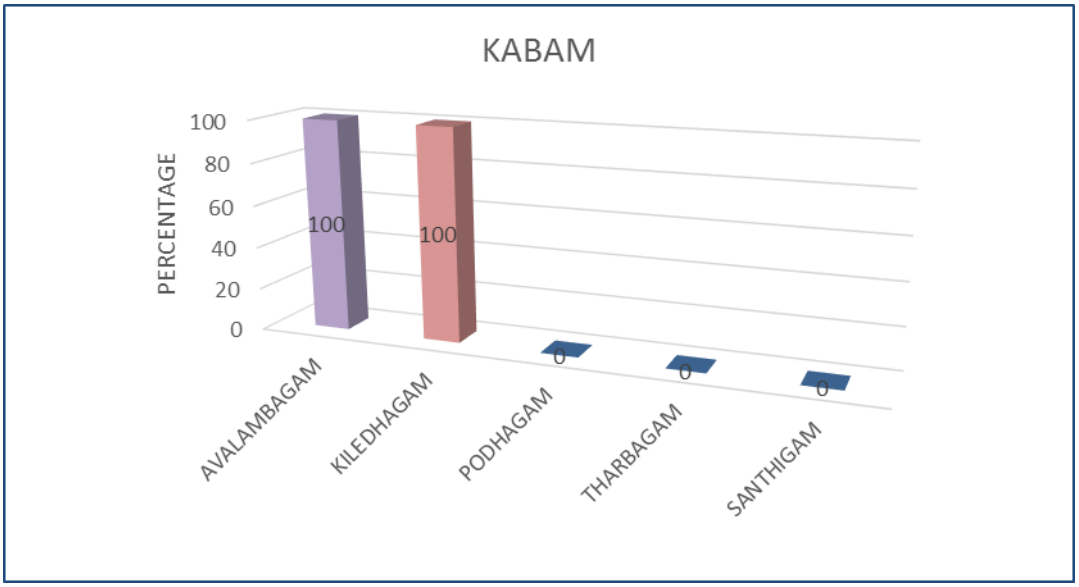


Inference:

Out of 30 patients, according to Pitham, Analapitham was affected in 100% of cases (Table 8b).

Table 8.c. Distribution of patients with *Kattu mantham* according to dearrangement of Kabam

S.No	Types of Kabham	No.of Cases	Percentage
1.	Avalambagam	30	100%
2.	Kilethagam	30	100%
3.	Pothagam	0	0
4.	Tharpagam	0	0
5.	Santhigam	0	0

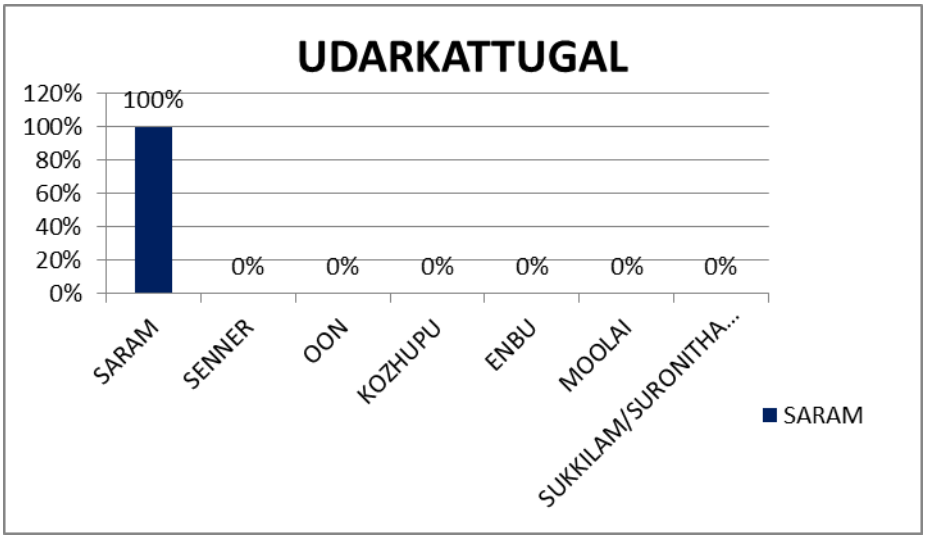


Inference:

According to Kabam, Avalambagam and Kilethagam were affected in 100% of cases (Table8c).

Table 9. Distribution of patients with *Kattu mantham* according to derangement of Ezhu Udarkattugal

S.No	Udarkattugal	No.of Cases	Percentage
1.	Saaram	30	100%
2.	Senneer	0	0
3.	Oon	0	0
4.	Kozhuppu	0	0
5.	Enbu	0	0
6.	Moolai	0	0
7.	Sukkilam / Suronitham	0	0

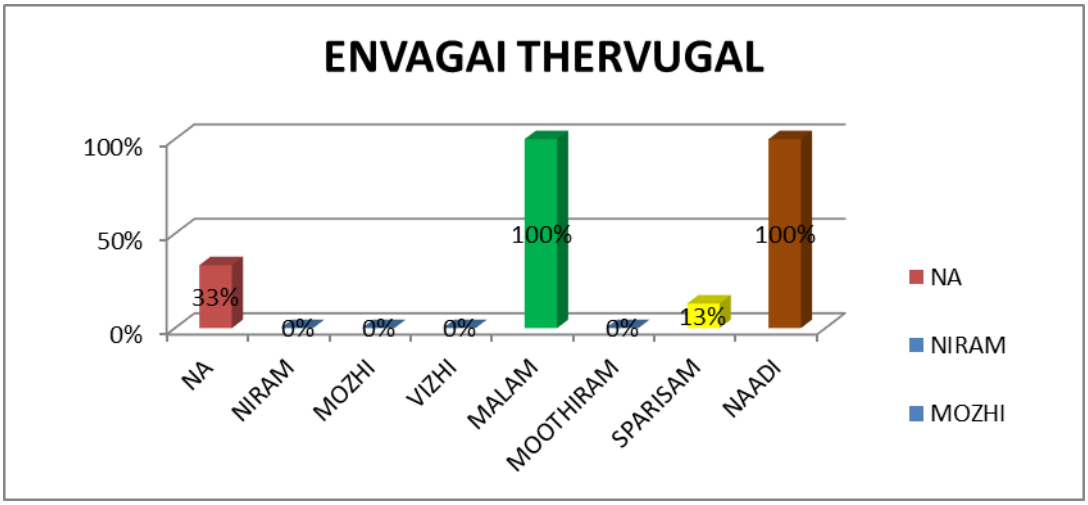


Inference:

Out of 30 patients, Saram was affected in 100% of cases. All other udarkattugalwas not affected in any cases (Table 9)**.**

Table 10. Distribution of patients with *Kattu mantham* according to derangement of Enn vagai thervugal

S.No	Enn Vagai Thervugal	No of Cases (Percentage%)
1	Naa	10 (33.3%)
2	Niram	0
3	Mozhi	0
4	Vizhi	0
5	Malam	30 (100%)
6	Moothiram	0
7	Sparisam	4 (13.3%)
8	Naadi	30 (100%)

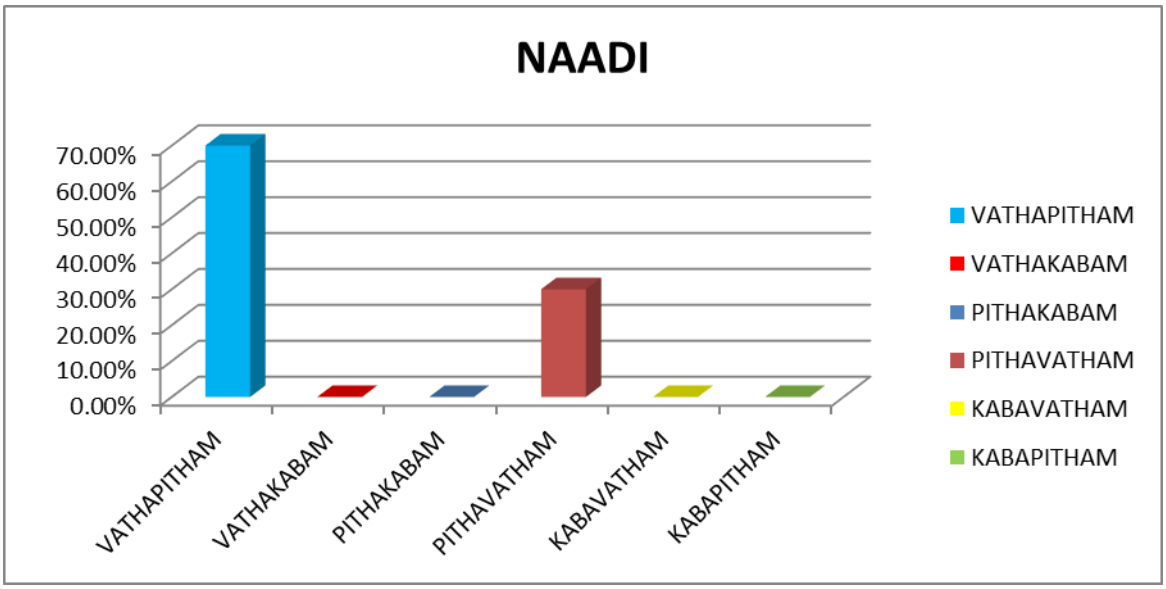


Inference:

Out of 30 cases, Malam was affected in 100% of cases, Sparism was affected in 13.3% of cases, Naa was affected in 33.3% of cases.(Table 10)

Table 11. Distribution of patients with *Kattu mantham* according to observation of Naadi

Naadi	No of Cases	Percentage
Vathapitham	21	70%
Vathakabam	0	0
Pithakabam	0	0
Pithavatham	9	30%
Kabapitham	0	0
Kabavatham	0	0

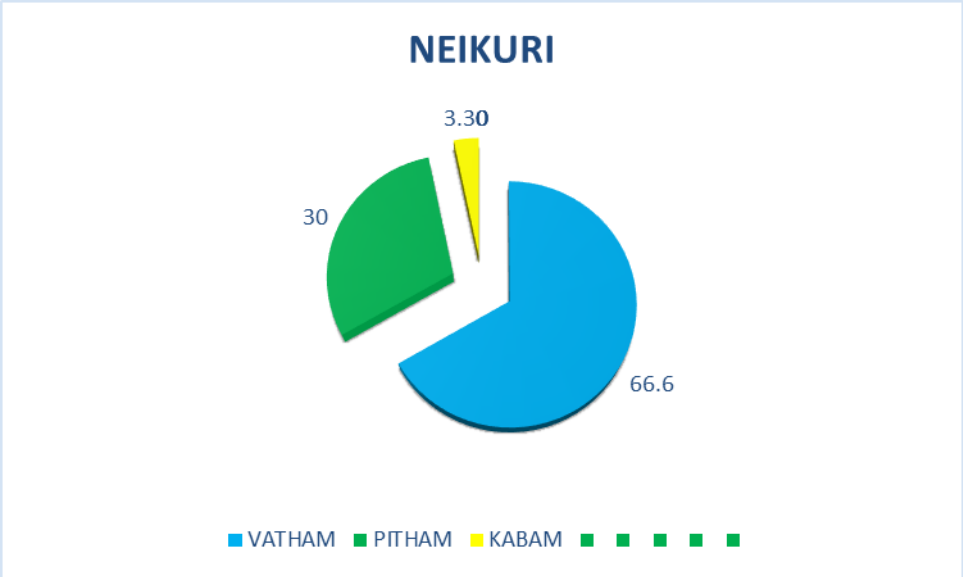


Inference (Naadi):

In Naadi, Vathapitham was observed in 70 % of cases, Pithavatham was observed in 30 % of cases

Table 12. Distribution of patients with *Kattu mantham* according to observation of Neikuri analysis

S.No	Character of urine	Neikuri Reference	No.of Cases	Percentage
1.	Spreads like snake	Vatha Neer	20	66.6
2.	Spreads like ring	Pitha Neer	9	30
3.	Static as pearl	Kaba Neer	1	3.3



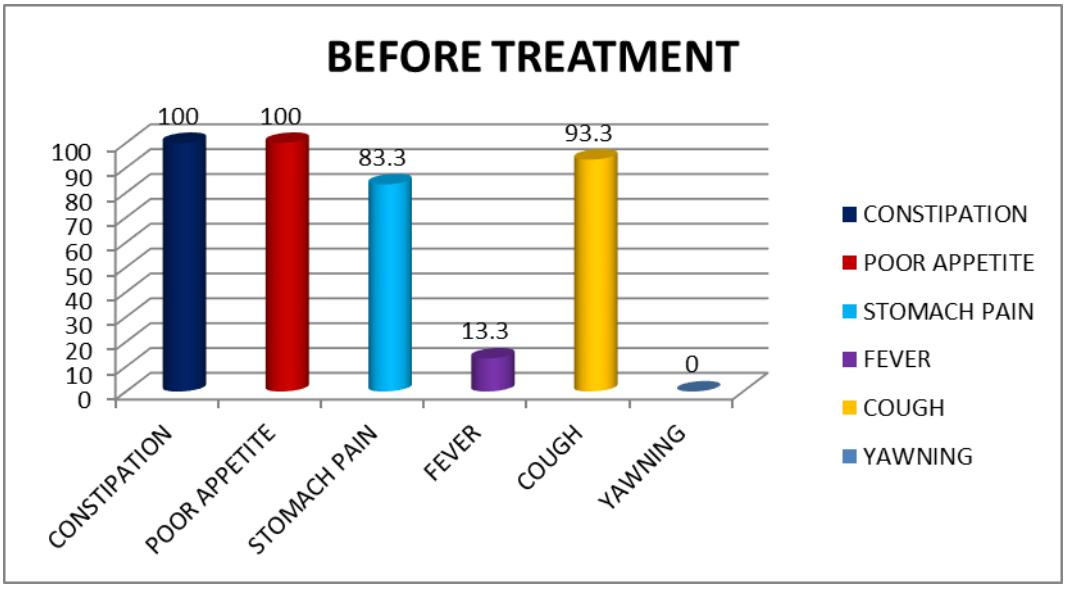
Inference

According to Neikuri, Vatha neer was observed in 66.6% of cases, pitha neer was observed in 30% of cases, Kaba neer was observed in 3.3 % of cases (Table 12)

Table – 13

Distribution of clinical symptoms of Kattu mantham

S.No	Signs and Symptoms	No.of cases (out of 30)	Percentage
1	Constipation	30	100%
2	Poor appetite	30	100%
3	Borborymus/stomachpain	25	83.3%
4	Fever	4	13.3%
5	Cough	28	93.3%
6	Yawning	0	0



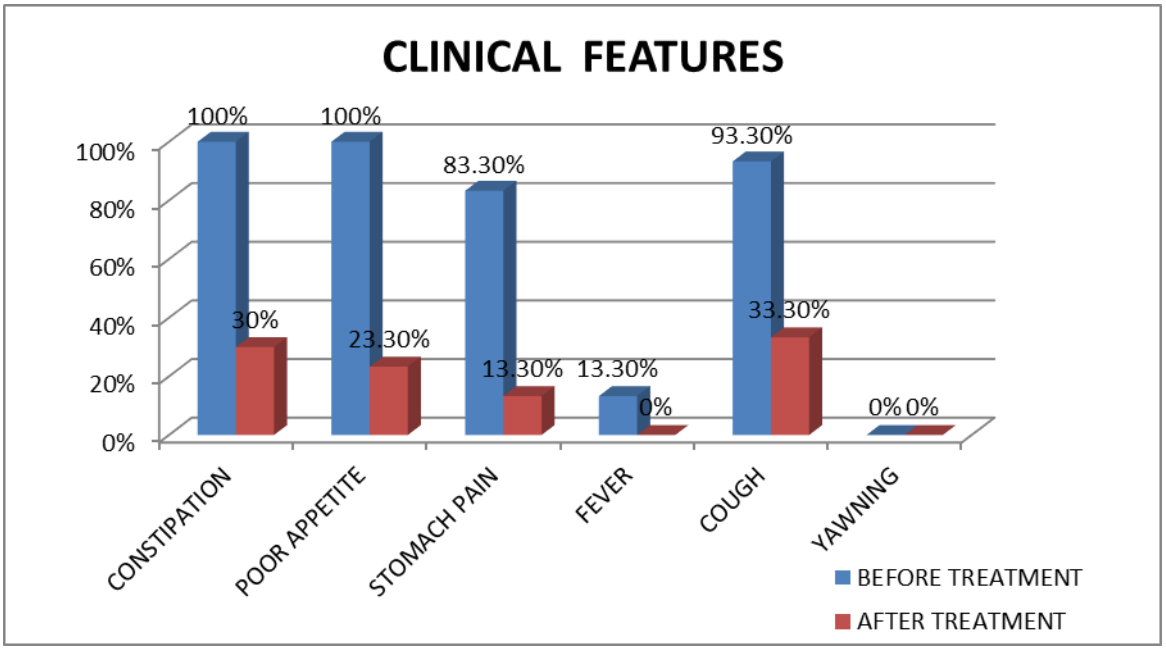
Inference

Among the 30 cases, 100% of the patients had constipation, 83.3 % had borborygmus/stomach pain, 100% had poor appetite, 13.3% had fever, 93.3% had cough. No patients (0%) was reported with yawning

Table – 14

Distribution of patients with *Kattu mantham* according treatment results obtained

Clinical Features	Before Treatment	Percentage (%)	After Treatment	Percentage (%)
Constipation	30	100%	9	30%
Poor appetite	30	100%	7	23.3%
Borborygmus/stomach pain	25	83.3%	4	13.3%
Fever	4	13.3%	0	0
Cough	28	93.3%	10	33.3%
Yawning	0	0	0	0



Inference:

Out of the 30 cases, the signs and symptoms like constipation 100 %, poor appetite100%, borborygmus/stomach pain 83.3%, fever 13.3%, cough 93.3% were reduced into 30%, 23.3%, 13.3%, 0%, 33.3% reuced respectively. These results were based on the clinical improvements observed.

For clinical studies

Statistical analysis:

All collected data were entered into MS Excel software using different columns as variables and rows as patients. STATA software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross- tabulations were performed. Bar diagram, Pie charts were used to describe the value of different variables for pictorial representation. The quantity variables were expressed as Mean and standard deviation and qualitative data as percentage. A probability value of less than 0.05 was considered to indicate as statistical significance. Paired't' test was performed for determining the significance between before and after treatment.

Paired Samples Statistics

S. No	Treatment	Mean ± SD	95% Confidence Interval of the Difference		Significance (t,p)
			Lower	Upper	
1	Before	1.27±0.450	1.1	1.43	t = -9.379 p<0.001
2	After	2.53±0.776	2.24	2.82	

RESULT

1. The mean ± standard deviation of clinical symptoms, before and after treatment were 1.27 ± 0.450 and 2.53 ± 0.776 respectively. which is statistically significant t-value = - 9.379, P value P<0.00
2. P<0.05- reject null hypothesis
3. There is a significance between before and after treatment
4. The result shows 70% reduction in the clinical symptoms of patients after treatment

CHAPTER VI

6. DISCUSSION

Kattu mantham is one of the most common illness in day to day life activities in children. Kattu mantham is defined as passing stools fewer than 2 times per week with abdominal discomfort, loss of appetite, lethargy sometimes with or without the symptoms of fever cough, nausea and vomiting. The clinical features of kattu mantham can be correlated to constipation in modern science. The aim of the trial was to evaluate the therapeutic effect of the drug to relieve constipation.

The simple and effective drug Chukku nei (internal) and Chinni thuvalai (external) which has been mentioned in siddha literature for the management of **kattu mantham** were selected and the study was conducted after the preparation of protocol further screened by screening commite of national institute of siddha and the trial was approved by institutional ethical committee (IEC) with approval no.NIS/IEC/2016/11-21/14.10.2016. Then the trial drug was registered in Clinical Trial Registry of India (CTRI) with Registration No: CTRI/2017/06/008801

The trial drugs were prepared by the author in the Gunapadam Practical Laboratory of National Institute of Siddha, after getting proper authentication of raw drugs from the Medicinal Botany Department at NIS, chennai 47. The trial drug was prepared by the standard operating procedure as mentioned in the protocol.

The biochemical qualitative and quantitative analysis of drugs were performed in Biochemistry Lab of NIS, Chennai. The safety of the trial drug usage through the biochemical analysis were also ensured during the study. The patients were recruited for the trial basd on inclusion and exclusion criteria and after getting the consent from the parent 30 patients were included in this study.

30 cases were treated in OPD of Ayothidoss Pandithar Hospital, National Institute of Siddha. Separate proforma was maintained for every patient. Daily progress were monitored.

The patients were treated with trial drugs Chinni thuvali (external therapy) at morning, after finishing the therapy patients were adviced to take bath with warm water. Then the trial drug Chukku nei was given orally with a dosage of 5 ml. OPD patients were instructed to come regularly for 3 days and advised to follow the diet.

The results observed during the study period were discussed below

Preclinical studies

Physicochemical analysis:

Acid value

The Acid value is used to quantify the substance, which is an index of free fatty acid content due to enzymatic activity. The acid value of chukku nei was found to be 3.104 mg KOH/g.

Peroxide value

The peroxide value is a measure of active oxygen in the oil and high starting level of peroxide value indicates the low quality of the oil. If the peroxide level is higher than 10meq/kg means that the stability of the oil is less and has a shorter shelf life. In this study the peroxide value is 2.325 meq/kg and it iscomparatively very low.therefore it is cleared that the oil has long shelf life.

Saponification value

The saponification value is 262.43 mh KOH/g to neutralize the fatty acids resulting from the complete hydrolysis of 1gm of sample.

Iodine value

Iodine value is used to evaluate the unsaturated level in fatty acids. A higher iodine value indicates the higher degree of unsaturation. In this study the iodine value is 172.08 mgI_2/g. Therefore, it is not too much hard in texture.

Determination of PH

Strongly acidic nature of the drug can cause the harmful effects to the body. So the screening for the pH is important for the drug. It represents the chemical nature of the drug and the site of absorption of non polar drug. The pH of Chukku nei is found to be 4 that is

weakly acidic and safe in pH. The weakly acidic drugs are rapidly absorbed from stomach. So the trial drug Chukku nei can act rapidly on oral administration.

Biochemical analysis

The Bio chemical analysis of trial medicines showed presence of calcium, magnesium, sulphate, zinc, Iron and alkaloids. Presence of tannic acid – drug containing tannins posses anti ulcer activity, it reduce symptoms of Abdomen discomfort. Presence of calcium – calcium ions significantly increase the drug release. It enhance the drug to absorb well.

Heavy metal analysis

Results shows that Chukku nei has no traces of Mercury and Arsenic. Lead and cadmium seems very low when compare to the allowed recommended limit. So there is no toxicity to the children while intake of medicine.

Analysis of organochlorine pesticide, organophosphorus pesticide and pyrethroid

There were no traces of pesticides residues such as Organo chlorine, Organo phosphorus Pesticides and pyrethroids.

Test for Aflatoxin

The results shown that there was no spots were been identified in the test sample loaded TLC plated when compare to the standard indicates that the sample were free from Aflatoxin B1, Aflatoxin B2, Aflatoxin G1, Aflatoxin G2.

Pharmacological Activity - In Vitro carminative Activity

In-vitro carminative activity of the Chukku nei was evaluated by modified method of Swapnil Sharma et al clearly indicates the test drug Chukku nei. The carminative profiling of the test sample Chukku nei was evaluated on basis of the amount of cabondioxide evolved from the reaction mixture with varying volume of Chukku nei.The maximum amount of Cabondioxide {g} produced by the 20ml of the sample Chukku nei wasfound to be (12.53 ± 0.53) and 40 ml of sample it was (16.17 ± 0.75) . It was concluded that the drug possesses promising carminative activity in the tested medium which was measured as an index of mass of CO_2 released from the medium.

Patients Demographic Parameters

Age:

In the present study, Out of 30 patients, 53.3% of cases were within 1-2 years, 46.6% were within2-3 years.

Sex:

Out of 30 patients 43.3% patients were male children and 56.6 % patients were female children. Female children affected more than male children.

Socio-economic status:

About 40% patients were under lower income group, 50% patients were under middle income group and 10%patients were under high income group. The highest incidence occurred in middle income group.

Seasonal variation:

According to paruva kaalam, high incidence of cases 50% were reported in munpanikalam, 46.6% cases were reported in pinpani kalam and 1% in koothirkalam.

Food habits:

According to food habits 30% of children are taking Vegetarian food and 70% of them from Non Vegetarian group. The highest incidence of cases was observed in Non vegetarian diet

Nilam:

Among 30 patients, 100% of cases from Neithal land.

Vali (Vatham)

Due to the derangement of vatha the following symptoms occur. Abanan was affected in 100% of cases and cause constipation .Viyanan was affected in 100%, Samanan was affected in 100% of cases. Uthanan was affected in 93.3% of cases cause cough, Kirukaran was affected in 100% cause cough, Poor appetite and devathathan was affected in 100% cause general body weakness.

Azhal (Pitham)

Analapitham was affected in 100% of cases cause poor appetite.

Iyyam (Kabam):

Avalambagam and Kilethagam was affected in 100 % of cases cause poor appetite.

Ezhu udarkattugal:

In Ezhu udar kattugal, Saram was affected in 100% of cases due to Cough and Poor appetite.

Envagai thervugal:

In envagai thervugal, Na was affected in 33.3% of cases, Malam was affected in 100% of cases due to constipation. Sparisam was affected in 13.3% of cases due to Low grade fever. Naadi was affected in 100% of cases.

Naadi:

Vathapitham was observed in 70% of cases, Pithavatham was observed in 30% of cases. According to naadi, high distribution observed in vali Azhal, Azhal vali naadi. In siddha literature, the character of vali Azhal is due to poor appetite, indigestion and nausea.

Neerkuri:

Regarding moothiram, neerkuri showed straw coloured urine in all cases.

Neikuri:

In the present study, vatha neer was observed in 66.6% of cases, pitha neer was observed in 30% of cases and kaba neer was observed in 3.3% of cases. According to this neikuri, vatham was dominately affected.

Clinical features:

The clinical feature of Kattu mantham may be correlated with clinical manifestations of Constipation. In accordance with the clinical features of *kattu mantham* among the 30 cases, Among the 30 cases, 100% of the patients had constipation, 83.3 % had borborygmus/stomach pain, 100% had poor appetite, 13.3% had fever, 93.3% had cough. No patients (0%) was reported with yawning

Improvement in clinical features:

Out of the 30 cases, the signs and symptoms like constipation 100 %, poor appetite100%, borborygmus/stomach pain 83.3%, fever 13.3%, cough 93.3% were reduced into 30%, 23.3%, 13.3%, 0%, 33.3% reuced respectively. These results were based on the clinical improvements observed.

Improvement in symptoms of Constipation using Bristol Stool Chart

Before treatment

Out of 30 cases, 22 (73.3%) patients had severe constipation and 8 (26.6%) patients had mild constipation.

After treatment

Out of 22 (73.3%) in severe constipation cases, 5 (16.6%) had not passed stools, remaining 17 (56.6%) patients were passed stools normally.

Out of 8 (26.6%) in mild constipation cases, 4 (13.3%) patients were passed stools normally remaining 4 (13.3%) patients had mild constipation.

Totally out of 30 cases, 21 (70%) had passed stools normally whereas remaining 5 (16.6%) patients had not passed stools and 4 (13.3%) patients had mild constipation.

Statistical analysis

The clinical efficacy of the drug was analyzed statistically on all the symptoms mentioned in the assessment criteria (t-value = - 9.379, $P<0.00$)are statistically significant

These results were based on the clinical improvements observed. The reduction of clinical symptoms after the treatment is significant. The reduction in the symptoms is 70% from the start of the treatment. Hence the medicine is good in effective.

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7. SUMMARY

The disease Kattu mantham was taken for the clinical study with Chukku nei (Internal) and Chinni thuvalai (External) after scrutinizing the research protocol by the Screening committee of National Institute of Siddha.

The Clinical studies were carried out after obtaining proper permission from approval IEC of National Institute of Siddha IEC No: NIS/IEC/2016/11-21/14.10.2016. The trial registered in Clinical trial Registry of India with Reg .No.CTRI//2017/06/008801. The Authentication of ingredients of the trial drug was done by Medicinal Botanist, National Institute of Siddha, Chennai.

Purification of raw drugs and preparation of trial drug was done in Gunapadam Laboratory of National Institute of Siddha, Chennai. Biochemical Qualitative analysis of trial drug was done in Biochemistry laboratory of National Institute of Siddha, Chennai. The biochemical analysis of trial medicine showed the presence of calcium, magnesium, sulphate, Iron and alkaloids.

Physicochemical analysis and In vitro carminative activity of Chukku nei were done in Noble research solutions, Chennai. The physicochemical analysis showed the trial drug is in appropriate consistency for trial study and it possesses promising carminative activity in the tested medium which was measured as an index of mass of CO_2 released from the medium.

All the 30 samples were recruited for this study from OPD of Kuzhandhai Maruthuvam department at Ayothidoss Pandithar Hospital of National Institute of Siddha. The patients with Kattu mantham were recruited based on Inclusion and Exclusion criteria and a detailed study was done. Separate proforma was maintained for each patient along with progress chart to monitor the prognosis.

The clinical efficacy of the trial drugs were analyzed statistically on all the symptoms mentioned in the assessment form. (t-value = - 9.379 and $P<0.00$ are statistically significant). The result shows that 70% reduction in the clinical symptoms and thus proves

the efficacy of the medicine. The patients have not complained of any adverse effects or difficulties during the course of treatment. Thus the drug is found to be safe and effective in the management of Kattu mantham. So the trail drugs *Chukku nei (Internal) and Chinni thuvalai (External)* was clinically effective.

8 .CONCLUSION

The Siddha system of medicines has certainity with safer medications to treat children. The children are in the age group of 1-3 years , who all diagnosed (30 patients) Kattu mantham were treated with Chukku nei (internal) 5ml, once at morning as well as Chinni thuvalai (external) for 3 days in Kuzhandhai Maruthuvam OPD of National Institute of Siddha.

The ingredients of the internal as well as extrernal medication are purely herbal and are easily available. The prepared medicine was palaptable and these compounds may serve as potentially useful drug at low cost.

Review of literature showed that most of the ingredients in the trial drug has effect in gastro intestinal tract like laxative and carminative activity. Thus was helpful in treating Kattu mantham in my study. The Clinical trial proves the efficiacy of the trial drug were found to be significant by relieving constipation, poor appetite, abdominal discomfort etc. The study shows that the Good improvement was found in 70% of cases after treatment.

The clinical trial conducted in the selected study group was satisfactory and in turn provided a further research and opportunity for new drug establishment in the management of *Kattu mantham.*

Because of the encouraging result of above study, the drug Chukku nei (internal) and Chinni thuvalai (external) may be taken for larger study with more number of sample population in the treatment of *Kattu mantham.*

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NATIONAL INSTITUTE OF SIDDHA,

AYOTHIDOSS PANDITHAR HOSPITAL,

CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) A SIDDHA DRUG IN THE TREATMENT OF KATTU MANTHAM (CONSTIPATION) IN CHILDREN.

SCREENING FORM -I

1. S.L No:	2. OP/ IP No:	3. Name:
4. Age:	5.Gender:	6. Date of Enrollment:
7. Date of completion:	8.Informant:	9. Reliablity:

INCLUSION CRETERIA:

	YES	NO
Age: between 1 - 3 years		
• Constipation	☐	☐
• Poor appetite	☐	☐
• Stomach pain / Borborygmus	☐	☐
• Fever	☐	☐
• Cough	☐	☐
• Yawning	☐	☐

EXCLUSION CRITERIA

• High temp > 102ºF	☐	☐
• Intolerable stomach pain	☐	☐
• Constipation more than 1 week	☐	☐
PATIENT SELECTED FOR TRIAL	☐	☐

IF YES ADMITTED IN IP ☐ OPD ☐

Signature of Investigator : Signature of Guide

NATIONAL INSTITUTE OF SIDDHA,

AYOTHIDOSS PANDITHAR HOSPITAL,

CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) A SIDDHA DRUG IN THE TREATMENT OF KATTU MANTHAM (CONSTIPATION) IN CHILDREN.

CONSENT FORM –II

CERTIFICATE BY INVESTIGATOR

I certify that I have disclosed all the details about the study in the terms readily understood by the parent/guardian

Signature _____

Date _____

Name _____ _____

CONSENT BY PARENT

I have been informed to my satisfaction, by the attending physician, the purpose of the clinical trial, and the nature of drug treatment and follow-up including the laboratory investigations to be performed to monitor and safeguard my son/daughter body functions.

I am aware of my right to opd my son/daughter out of the trail at any time during the course of the trail without having to give the reasons for doing so.

I, exercising my free power of choice, hereby give my consent to include my son/daughter as a subject in the clinical trial of **"*CHUKKU NEI" (INTERNAL) and "CHINNI THUVALAI" (EXTERNAL)*** for the treatment of ***KATTU MANTHAM*** **(CONSTIPATION)** in children

Date : Signature _____

Name _____

Signature of witness _____

தேசிய சித்த மருத்துவ நிறுவனம்
அயோத்திதாச பண்டிதர் மருத்துவமனை சென்னை47
குழந்தை மருத்துவத்துறை

"சுக்கு நெய்" (உள் மருந்து) மற்றும் "சின்னித்துவளை" (பிற மருந்து) பரிகரிப்பு திறனை கண்டறியும் மருத்துவ ஆய்வு

ஒப்புதல் படிவம் – ஆய்வாளரால் சான்றளிக்கப்பட்டது.

நான் இந்த மருத்துவ ஆய்வை குறித்த அனைத்து விபரங்களையும் நோயாளின் பெற்றோருக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதிஅளிக்கிறேன்.

தேதி: கையொப்பம்:

இடம்: பெயர்:

நோயாளியின்பெற்றோர்ஒப்புதல்படிவம்

என்னிடம் இந்த மருத்துவ ஆய்வின் காரணத்தையும் மருந்தின் தன்மை மற்றும் மருத்துவ வழி முறைபற்றியும்@ இந்த மருத்துவத்தை தொடர்ந்து எனது குழந்தையின் உடல் இயக்கத்தைக் கண்காணிக்கவும் அதனை பாதுகாக்க பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றியும் திருப்தி அளிக்கும் வகையில் ஆய்வுமருத்துவரால் விளக்கிகூறப்பட்டது.

நான் இந்த மருத்துவ ஆய்வின் போது எப்போது வேண்டுமானாலும் என் குழந்தையை விடுவித்துக் கொள்ளும் உரிமையை தெரிந்திருக்கிறேன்.

நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு கட்டு மாந்தம் நோய்க்கான "சுக்கு நெய்" (உள்மருந்து) மற்றும் "சின்னித்துவளை" (பிறமருந்து) பரிகரிப்புத் திறனை கண்டறியும் மருத்துவ ஆய்வுக்கு எனது குழந்தையை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி; பெற்றோர் பெயர்:

இடம்: கையொப்பம்:

சாட்சிக்காரர்பெயர்:

உறவுமுறை:

கையொப்பம்:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL,CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) IN THE TREATMENT OF KATTU MANTHAM (CONSTIPATION) IN CHILDREN

FORM III - CASE REPORT FORM

Demographic data

Sl No :	OP/IP No.	Visit Date : (__/__/____)
Name :		
Age :		
Gender Male ☐ Female ☐		Date Of Birth : (__/__/____)
Father/ Mother /Guardian Name :		
Father's Occupation :		
Father's Monthly Income :		
Religion :		
Socioeconomic Status :		
Patient Informant :		
Postal Address : Contact no :		

1. Complaints and duration

2. History of Present illness

3. History of Past Illness

History /Symptoms/Signs	**Yes**	**No**	**If, Yes Details**
Any Similar Complains	☐	☐	_____
Dust Allergy	☐	☐	_____
Hospitalization	☐	☐	_____
Any other	☐	☐	_____ _____

Family History

Any Hereditary/ Familial Disease Yes No

If Yes, Details --------

Immunization History

Proper Immunization given Yes ☐ No ☐ .....

Food habits:

1. Veg ☐ 2. Non-Veg ☐ 3. Mixed ☐

General examination

Pallor	YES	☐	NO	☐
Jaundice	YES	☐	NO	☐
Cyanosis	YES	☐	NO	☐
Clubbing	YES	☐	NO	☐
Pedal oedema	YES	☐	NO	☐
Lymph adenopathy	YES	☐	NO	☐

Vital signs:-

1. Pulse rate /min : _____
2. Heart rate /min : _____
3. Respiratory rate /min : _____
4. Temperature : _____

Anthropometry:-

Height : _____ cm

Weight : _____ kg

CLINICAL EXAMINATION:

GASTRO INTESTINAL SYSTEM

a) INSPECTION :

Shape of the abdomen	- Distended ☐	Scaphoid ☐
Abdominal movements	- Inverted ☐	Everted ☐
Scars	- Absent ☐	Present ☐
Visible veins	- Absent ☐	Present ☐
Peristaltic waves	- Absent ☐	Present ☐
Pulsations	- Absent ☐	Present ☐
Groin/scrotum	- Normal ☐	Affected ☐

b) PALPATION :

	Absent	**Present**	**Remarks**
Skin turgor	☐	☐	_____
Abnormal masses	☐	☐	_____
Tenderness	☐	☐	_____

C) PERCUSSION:

Shifting dullness	☐	☐	_____
Fluid thrill	☐	☐	_____
Tympanic resonance note	☐	☐	_____

d) AUSCULTATION:

Bowel sounds : Absent ☐ Normal ☐ Increased ☐ Decreased ☐

Examination of Other systems;

	Normal	Affected
Cardio vascular system:	☐	☐
Respiratory system	☐	☐
Musculo skeletal system:	☐	☐
Central nervous system:	☐	☐
Genito urinary system:	☐	☐

SYSTEMIC EXAMINATION (SIDDHA)

Nilam:-

Kurinji ☐ Mullai ☐ Marutham ☐ Neithal ☐ Paalai ☐

KaalaIyalbu:-

Kaarkalam ☐	Koothirkaalam ☐	Munpanikaalam ☐
Pinpanikaalam ☐	Illavenirkaalam ☐	Muthuvenirkaalam ☐

Yaakai

Vatham ☐	VathaPitham ☐	VathaKabam ☐
Pitham ☐	Pithavatham ☐	PithaKabam ☐
Kabam ☐	KabaVatham ☐	KabaPitham ☐

Gunam

Sathuvam ☐ Rasatham ☐ Thamasam ☐

Pori / Pulangal

	Normal	Affected	Remarks
Mei / unarvu	☐	☐	_____
Vaai / suvai	☐	☐	_____
Kan / parvai	☐	☐	_____
Mooku / natram	☐	☐	_____
Sevi / olli	☐	☐	_____

Kanmendhirium / Kanmavidayam

	Normal	Affected	Remarks
Kai / dhanam	☐	☐	_____
Kaal / ghamanam	☐	☐	_____
Vaai / vaku	☐	☐	_____
Eruvaai / visarkam	☐	☐	_____
Karuvaai / anantham	☐	☐	_____

Uyir Thathukkal Vatham:

	Normal	Affected	Remarks
Pranan	☐	☐	_____
Abanan	☐	☐	_____
Viyanan	☐	☐	_____
Uthanan	☐	☐	_____
Samanan	☐	☐	_____
Nagan	☐	☐	_____
Koorman	☐	☐	_____
Kirukaran	☐	☐	_____
Devathathan	☐	☐	_____
Dhanajeyan	☐	☐	_____

Pitham

	Normal	Affected	Remarks
Analagam	☐	☐	_____
Ranjagam	☐	☐	_____
Saathagam	☐	☐	_____
Alosagam	☐	☐	_____
Prasagam	☐	☐	_____

Kabam

	Normal	Affected	Remarks
Avalambagam	☐	☐	_____
Kilethagam	☐	☐	_____
Pothagam	☐	☐	_____
Tharpagam	☐	☐	_____
Santhigam	☐	☐	_____

Udal Thathukkal

	Normal	Affected	Remarks
Saaram	☐	☐	_____
Senneer	☐	☐	_____
Oon	☐	☐	_____
Kozhuppu	☐	☐	_____
Enbu	☐	☐	_____
Moolai	☐	☐	_____
Sukilam / Suronitham	☐	☐	_____

EnvagaiThervugal

	Normal	Affected	Remarks
Naa			
Niram	☐	☐	_____
Thanmai	☐	☐	_____
Suvai	☐	☐	_____
Niram	☐	☐	_____
Mozhi	☐	☐	_____
Vizhi	☐	☐	_____
Niram	☐	☐	_____
Thanmai	☐	☐	_____
Parvai	☐	☐	_____

Sparisam

Malam

Niram Normal ☐ Affected ☐ _____

Nurai Normal ☐ Affected ☐ _____

Elagal Normal ☐ Affected ☐ _____

Erugal Normal ☐ Affected ☐ _____

Moothiram

Neerkuri: Niram Normal ☐ Affected ☐ _____

Edai Normal ☐ Affected ☐ _____

Nurai Normal ☐ Affected ☐ _____

Manam Normal ☐ Affected ☐ _____

Enjal Normal ☐ Affected ☐ _____

Neikuri:

Vatham ☐ _____

Pitham ☐ _____

Kabam ☐ _____

Other ☐ _____

Naadi :

Thani Nadi

Vadham ☐ pitham ☐ kabam ☐

Thontha Nadi

Vathapitham ☐ Pithavatham ☐ Pithakabam ☐ Kabapitham ☐

Vathakabam ☐ Kabavatham ☐

Diagnosis ----------

Admitted to trial: 1. Yes ☐ 2. No ☐

If yes, S. No: 1.IP ☐ 2.OP ☐

DRUGS ISSUED:_____

Date : _____ Station : _____

Signature of Investigaton;

FORM IV PATIENT INFORMATION SHEET

Name of Principal Investigator : _____

Name of the institute **:** National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

INFORMATION SHEET FOR PATIENTS PARTICIPATING IN THE OPEN CLINICAL TRIAL.

I ---------- Studying as PG Scholar in department of Kuzhandhai Maruthuvam at National Institute of Siddha, Tambaram Sanatorium is doing a open clinical study on "Kattu Mantham" (Constipation). In this regard I am in a need to ask you few questions about your child's illness. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You have the liberty in taking part in the study or not to take part.you can choose not to answer a specific question. You may be benefited if you take part in this study. In addition to taking part in the study may be benefit to the community, as it may help us to understand the disease elaborately and its potential problem and potential solutions.

All the medicines and other relevant Investigation procedures will be provided with free of cost. If you agree that your child to be a participant in this study, he/she will be included in the study primarily by signing the consent form and then internal medicine CHUKKU NEI" will be given at a dose of 5 ml od at morning time and "CHINNI THUVALAI" will be done as external therapy for 3 days.

The information I am collecting in this study will remain between you and the investigator (myself). If you wish to find out more about this study before taking part, you can ask me all the related questions about the study and contact me (Dr. M. Lavanya, PG Scholar) through my mobile number 8508117010. You can also contact the Member - secretary of Ethics committee, National Institute Siddha, Chennai 600047, Tel no :91-44-22380789, for rights and participation in the study.

Place Signature of the investigator:

Date Name :

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) FOR KATTU MANTHAM (CONSTIPATION) IN CHILDREN.

FORM VI CLINICAL ASSESSMENT

1. S.l. No: 2. OP/ IP No : 3. Name:

4. Age: 5. Gender : 6. Date of Enrollment:

7. Date of completion: 8. Informant : 9. Reliablity:

S.NO	CLINICAL FEATURES	DAY 0		DAY 4	
		YES	NO	YES	NO
1	Constipation				
2	Poor appetite				
3	Stomach pain / borborygmus				
4	Fever				
5	Cough				
6	Yawning				

Date : _____

Station : _____ Signature of Investigator

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) FOR KATTU MANTHAM (CONSTIPATION) IN CHILDREN.

FORM V – DRUG COMPLIANCE

1. S.l. No:	2. OP/ IP No :	3. Name:
4. Age:	5. Gender :	6. Date of Enrollment:
7. Date of completion:	8. Informant :	9. Reliablity:

NAME OF THE DRUG : CHUKKU NEI

FORM OF THE DRUG : OIL

ADMINISTRATION : PER ORAL

DOSE AND DURATION : 5 ML (OD) FOR 3 DAYS

DAY	DATE	MORNING
1		
2		
3		

Date:

Station: Signature of the Investigator:

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) FOR KATTU MANTHAM (CONSTIPATION) IN CHILDREN.

FORM VII WITHDRAWL FORM

1. S.l. No:	2. OP/ IP No :	3. Name:
4. Age:	5. Gender:	6. Date of Enrollment:
7. Date of completion:	8. Informant:	9. Reliablity:

Date of trial commencement	:
Date of withdrawal from trial	:
Reason(s) for withdrawal	: Yes/ No
Long absence at reporting	: Yes/ No
Irregular treatment	: Yes/ No
Shift of locality	: Yes/ No
Complication adverse reactions if any	: Yes/ No
Exacerbation of symptoms	: Yes/ No
Patient not willing to continue	: Yes/ No

Date: Signature of Principal Investigator

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) FOR KATTU MANTHAM (CONSTIPATION) IN CHILDREN.

FORM VIII-ADVERSE REACTION

1. S.l. No:	2. OP/ IP No :	3. Name:
4. Age:	5. Gender:	6. Date of Enrollment:
7. Date of completion:	8. Informant:	9. Reliablity:

Registration No :

Date of trial commencement :

Date of withdrawal from trial :

Description of adverse reaction :

Date: Signature of Principal Investigator

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

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FORM IX – PHARMACOVIGILANCE FORM

1. Patient / consumer identification (please complete or tick boxes below as appropriate)

NATIONAL PHARMACOVIGILANCE PROGRAMME FOR SIDDHA DRUGS

Reporting Form for Suspected Adverse Reactions to Siddha Drugs

Please note: i.All consumers / patients and reporters information will remain confidential.

ii. It is requested to report all suspected reactions to the concerned, even if it does not have complete data, as soon as possible.

Peripheral Center code: State:

Name	Father name	Patient / Record No.
Ethnicity	Occupation	
Address Village / Town Post / Via District / State		Date of Birth / Age: Sex: Male / Female Weight : Degam:

2. Description of the suspected Adverse Reactions (please complete boxes below)

Date and time of initial observation		Season:
Description of reaction		Geographical area:

3. List of all medicines / Formulations including drugs of other systems used by the patient during the reporting period:

Medicine	**Daily dose**	**Route of administration & Vehicle – Adjuvant**	**Date**		**Diagnosis for which medicine taken**
			Starting	**Stopped**	
Siddha					
Any other system of medicines					

4. Brief details of the Siddha Medicine which seems to be toxic :

Details	**Drug – 1**	**Drug – 2**	**Drug - 3**
a) Name of the medicine			
b) Manufacturing unit and batch No. and date			
c) Expiry date			
d) Purchased and obtained from			
e) Composition of the formulation / Part of the drug used			

b) Dietary Restrictions if any

c) Whether the drug is consumed under Institutionally qualified medical supervision or used as self medication.

d) Any other relevant information.

5. Treatment provided for adverse reaction:

6. The result of the adverse reaction / side effect / untoward effects (please complete the boxes below)

<table>
<tr><td>Recovered:</td><td>Not recovered:</td><td>Unknown:</td><td>Fatal:</td><td>If Fatal
Date of death:</td></tr>
<tr><td rowspan="2">Severe: Yes / No.</td><td colspan="4">Reaction abated after drug stopped or dose reduced:</td></tr>
<tr><td colspan="4">Reaction reappeared after re introduction:</td></tr>
</table>

Was the patient admitted to hospital? If yes, give name and address of hospital	

7. Any laboratory investigations done to evaluate other possibilities? If Yes specify:

8. Whether the patient is suffering with any chronic disorders?

Hepatic Renal Cardiac Diabetes Malnutrition

Any Others

9. H/O previous allergies / Drug reactions:

10. Other illness (please describe):

11. Identification of the reporter:

Type (please tick): Nurse / Doctor / Pharmacist / Health worker / Patient / Attendant / Manufacturer / Distributor / Supplier / Any others (please specify)
Name:
Address:
Telephone / E – mail if any :

Signature of the reporter: **Date:**

Please send the completed form to:

Name & address of the RRC-ASU/ PPC-ASU

The Director
National Institute of Siddha,
Centre For Siddha Medicine),
Tambaram Sanatorium, Chennai-600 047.
Fax : 044 – 22381314
Website :www.nischennai.org
Email: nischennaisiddha@yahoo.co.in

*** ***

This filled-in ADR report may be sent within one month of observation /occurrence of ADR

Who Can Report?

⇒ Any Health care professionals like Siddha Doctors / Nurses / Siddha Pharmacists / Patients etc.

What to Report?

⇒ All reactions, Drug interactions,

Confidentiality

⇒ The patient's identity will be held in strict confidence and protected to the fullest extent.

⇒ Submission of report will be taken up for remedial measures only not for legal claim

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, CHENNAI – 600 047.

DEPARTMENT OF KUZHANDHAI MARUTHUVAM

A CLINICAL EVALUATION OF CHUKKU NEI (INTERNAL) AND CHINNI THUVALAI (EXTERNAL) FOR KATTU MANTHAM (CONSTIPATION) IN CHILDREN.

FORM IX-DIETARY ADVICE FORM

✓ THINGS TO TAKE	× THINGS TO AVOID
Fruits-Fig,Papaya,Gauva,Grapes,Bananas, apples, orange,dates	Refridged items
All greens eg-palak	Tin and canned foods
Fresh vegetable soups	Cream containing biscuits and cakes
Boiled water	Junk and fast foods
Fiber rich foods eg-whole-grain breads and cereals,almonds,legumes	White sugar, Maida

NATIONAL INSTITUTE OF SIDDHA- राष्ट्रीय सिद्ध संसथान
Ministry of AYUSH- आयुष मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार
TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियमचेन्नई -600 047
फ़ोन\Tele : 044-22411611 फैक्स\Fax : 22381314
ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/15-16 Dt: 14.10.2016

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr. M.Lavanya – I year, Dept.of Kuzhanthai Maruthuvam	
Protocol Title:- Clinical Evaluation of Chukku Nei (Internal) and Chinni Thuvalai (External) in the treatment of Kattu Mantham (Constipation) in Children.	
Documents filed	1) Protocol, 2) Data Collection forms
Clinical trial Protocol (others – Specify)	**Yes-(M.D-Dissertation)**
Informed consent documents	**Yes**
Any other documents	-
Date of IEC approval & its number	**NIS/IEC/2016/11-21/ 14.10.2016**

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

(Dr.V.Subramanian)
Chairman

NATIONAL INSTITUTE OF SIDDHA ★ CHENNAI 600 047

V. Banumathi 14/10/16

(Prof.Dr.V.Banumathi)
Member Secretary

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Chinni Thuvalai"** (External) taken up for Post Graduation Dissertation studies by **Dr.M.Lavanya** M.D.(S), II year, Department of Kuzhandhai Maruthuvam, 2017, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Acalypha fruticosa Forsk. (Euphorbiaceae), Leaves
Vitex negundo Linn. (Verbenaceae), Leaves
Azadirachta indica A. Juss. (Meliaceae), Leaves
Tinospora cordifolia (Willd.) Meirs (Menispermaceae), Leaves.

MEDICINAL BOTANY CHENNAI 600 047 National Institute of Siddha

Certificate No: NISMB2992017

Date: 12-06-17

Authorized Signatory
Dr. D. ARAVIND, M.D.(s),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047, INDIA

SASTRA UNIVERSITY

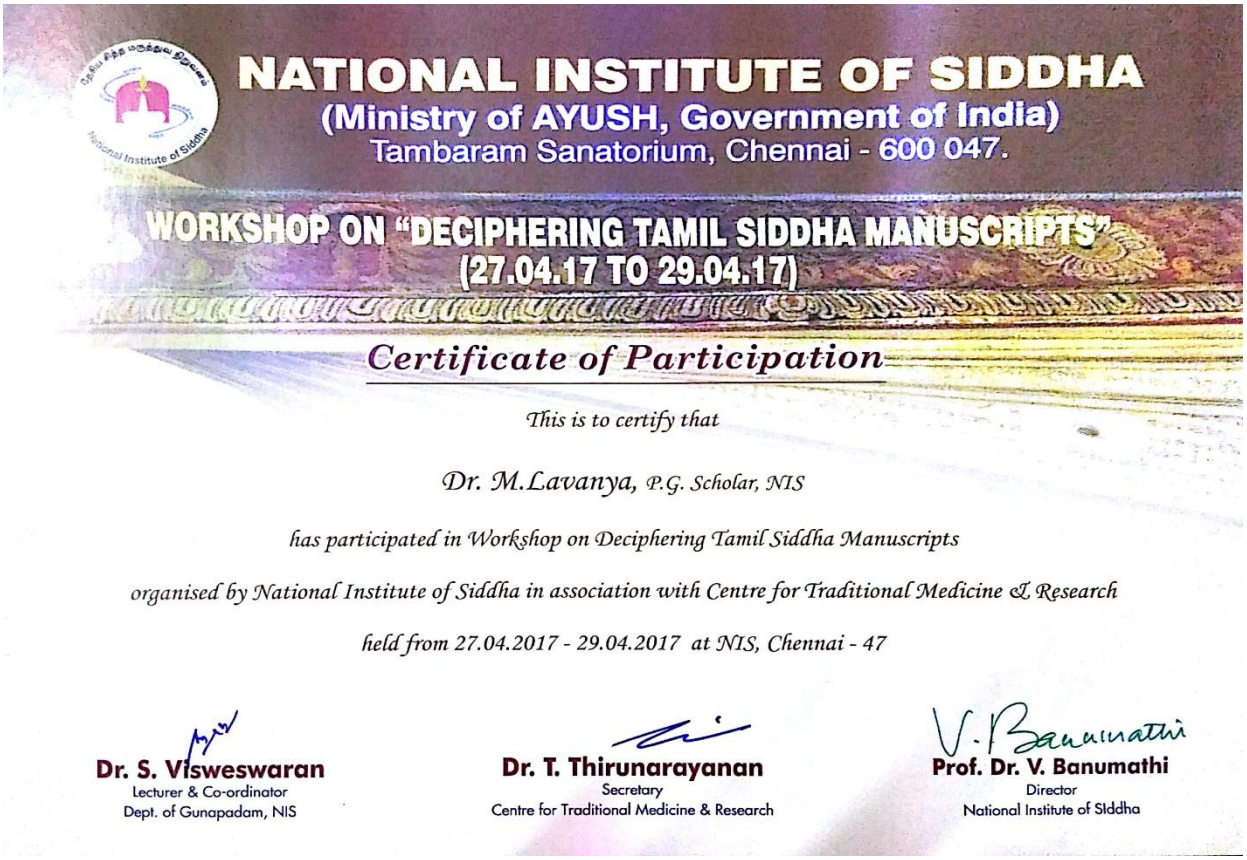
Centre For Advanced Research In Indian System Of Medicine (CARISM)

Certificate of Participation

This is to certify that Dr. M.LAVANYA of National Institute of Siddha, Chennai participated in Ministry of AYUSH supported training programme on **"Characterization Techniques in the Standardization of Ayurvedha & Siddha Herbo-Metallic Preparations"** held during 28 to 30 march 2016.

P. Brindha
Convener
Prof. P. Brindha

Registrar
SASTRA University



NATIONAL INSTITUTE OF SIDDHA

(Ministry of AYUSH, Government of India)

Tambaram Sanatorium, Chennai - 600 047.

WORKSHOP ON "DECIPHERING TAMIL SIDDHA MANUSCRIPTS"

(27.04.17 TO 29.04.17)

Certificate of Participation

This is to certify that

Dr. M.Lavanya, P.G. Scholar, NIS

has participated in Workshop on Deciphering Tamil Siddha Manuscripts

organised by National Institute of Siddha in association with Centre for Traditional Medicine & Research

held from 27.04.2017 - 29.04.2017 at NIS, Chennai - 47

Dr. S. Visweswaran
Lecturer & Co-ordinator
Dept. of Gunapadam, NIS

Dr. T. Thirunarayanan
Secretary
Centre for Traditional Medicine & Research

Prof. Dr. V. Banumathi
Director
National Institute of Siddha

Clinical Trial Details (PDF Generation Date :- Wed, 04 Jul 2018 09:37:47 GMT)

CTRI Number	CTRI/2017/06/008801 [Registered on: 09/06/2017] - **Trial Registered Prospectively**
Last Modified On	08/06/2017
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Siddha
Study Design	Single Arm Trial
Public Title of Study	Clinical Evaluation Of Chukku Nei and Chinni Thuvalai In The Treatment Of Kattu Mantham in Children
Scientific Title of Study	Clinical Evaluation Of Chukku Nei (Internal) and Chinni Thuvalai (External) In The Treatment Of Kattu Mantham (Constipation) In Children

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	M Lavanya
Designation	pg scholar
Affiliation	National Institute Of Siddha
Address	kuzhandhai maruthuvam,National Institute Of Siddha,Tambaram Sanatorium,Chennai kuzhandhai maruthuvam,National Institute Of Siddha,Tambaram Sanatorium,Chennai Chennai TAMIL NADU 600047 India
Phone	9791337194
Fax	
Email	lavanyacuety@gmail.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	K Suresh
Designation	Lecturer
Affiliation	National Institute Of Siddha
Address	kuzhandhai maruthuvam,National Institute Of Siddha,Tambaram Sanatorium,Chennai kuzhandhai maruthuvam,National Institute Of Siddha,Tambaram Sanatorium,Chennai Chennai TAMIL NADU 600047 India
Phone	9962571137
Fax	
Email	drsureshherbal@gmail.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	M Meenakshi Sundaram
Designation	Associate Professor
Affiliation	National Institute Of Siddha
Address	kuzhandhai maruthuvam,National Institute Of Siddha,Tambaram Sanatorium,Chennai kuzhandhai maruthuvam,National Institute Of Siddha,Tambaram Sanatorium,Chennai Chennai TAMIL NADU

	600047 India
Phone	9940266442
Fax	
Email	mmssiddha@gmail.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> National Institute Of Siddha,Tambaram sanatorium ,Chennai

Primary Sponsor

Primary Sponsor Details	
Name	Dr M Lavanya
Address	kuzhandhai maruthuvam,National Institute Of Siddha,Tambaram Sanatorium,Chennai
Type of Sponsor	Research institution and hospital

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
M Lavanya	National Institute Of Siddha,	kuzhandhai maruthuvam (8), National Institute Of Siddha,Tambaram Sanatorium , Chennai Chennai TAMIL NADU	979133714 lavanyacuety@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Committee	Approved	14/10/2016	No

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	patients with complaints of constipation,abdominal pain

Intervention / Comparator Agent

Type	Name	Details
Intervention	Chukku Nei (Intertnal) & Chinni Thuvalai (External)	Chukku Nei 5 ml bid for 3 days, Chinni thuvalai external for 3 days
Comparator Agent	-	-

Inclusion Criteria

Inclusion Criteria	
Age From	1.00 Year(s)
Age To	3.00 Year(s)
Gender	Both
Details	1 constipation 2 poor appetite 3 stomach pain/rumbling noise in stomach 4 fever 5 cough 6 yawning patients satisfying atleast 5 or more above criteria will be included in

	this study

Exclusion Criteria

Exclusion Criteria	
Details	1 high temperature>101 f 2 intolerable stomach pain 3 constipation more than 1 week 4 patient not willing to give biological samples whenever needed

Method of Generating Random Sequence	
Method of Concealment	
Blinding/Masking	

Primary Outcome

Outcome	Timepoints
clinical efficacy of the trial drug will be analysed through constipation scoring scale	24 months

Secondary Outcome

Outcome	Timepoints
clinical efficacy of the trial drug will be analysed through constipation scoring scale	24 months

Target Sample Size	**Total Sample Size=**30 **Sample Size from India=**30
Phase of Trial	Phase 2
Date of First Enrollment (India)	10/06/2017
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**2 **Months=**0 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Not Yet Recruiting
Publication Details	NIL
Brief Summary	clinical evaluation of chukku nei (internal) and chinni thuvalai (external) for kattu mantham (constipation) in children

Noble research solutions
We Trust in Quality and Ethics

Noble Research Solutions

We Trust in Quality and ethics

E-mail : nobleresearchsolutions@gmail.com
info@nobleresearchsolutions.com
Contact : 9710437419, Admin : 044 - 42691289

Date: 20.03.2018

To,

Dr.M.Lavanya
National Institute of Siddha,
Tambaram Sanatorium, Chennai 600047, Tamil Nadu, India.

Project Id: **NRS/AS/0087/01/2018**

This is to certify that Dr.M.Lavanya from National Institute of Siddha, Tambaram Sanatorium, Chennai, has carried out the following activity at our facility for the trial drug *Chukku Nei (CN)*

S.No	Study Description	Annexure no
1.	Standardization and Physicochemical Evaluation of study drug *Chukku Nei (CN)*	I
2.	In-vitro Anti-Carminative Activity	II

Note:

- *Annexures was attached as a separate enclosure along with this report.*

NOBLE RESEARCH SOLUTIONS TAMIL NADU INDIA CHENNAI

for NOBLE RESEARCH SOLUTIONS

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